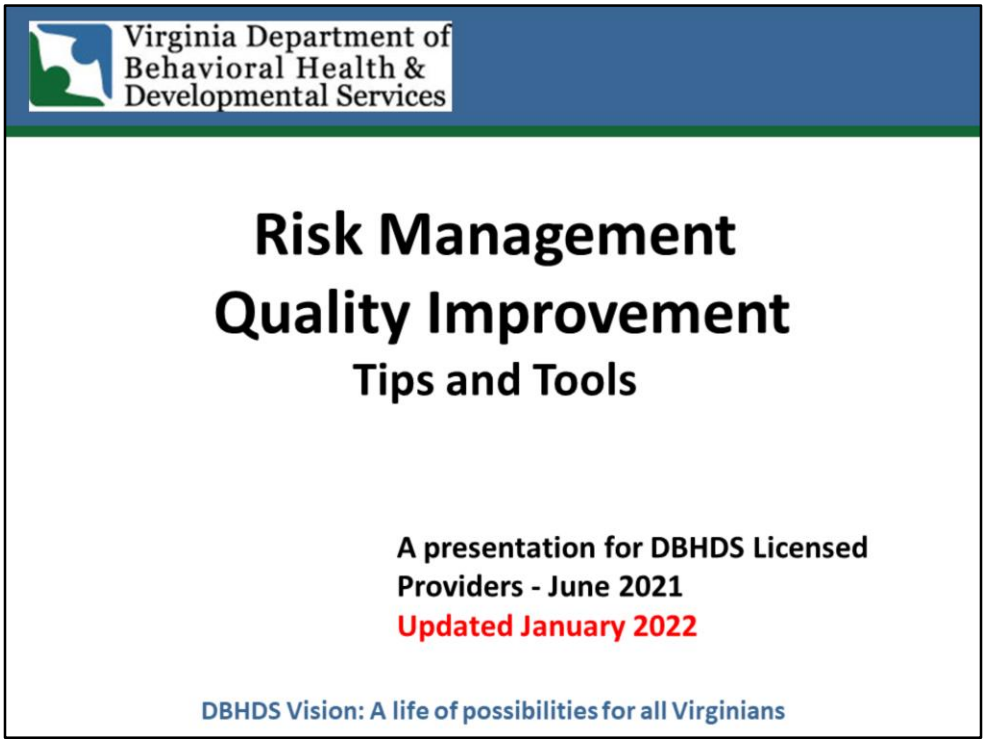
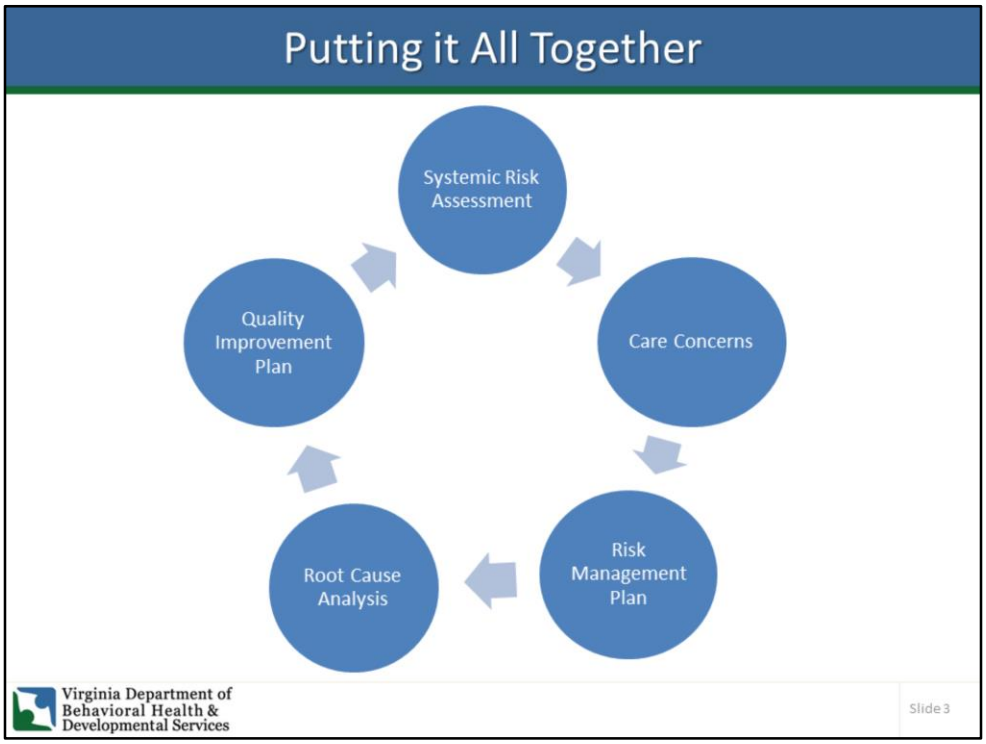


This power point presentation was updated to reflect the Office of Licensing's October 2021 announcement related to Care Concerns. In addition, the Questions and Answers (Q&A) from the training have been incorporated into this document.

The goals of this presentation are limited to risk management and quality improvement as it relates to the Rules and Regulations for Licensed Providers. An internet search for information on risk management, quality improvement and/or systemic risks assessments would provide lots of information, but today we are focusing on what the regulations require and some tips on what a provider should consider when developing their quality improvement plan, risk management plan and systemic risk assessment. The examples provided are just that – examples – and not intended to be a one size fits all. There is no required template to use. Providers should determine what works best for your organization.

On June 4, 2021, the Office of Licensing issued a Constant Contact with sample documents attached. The SAMPLES are posted on the Office of Licensing webpage. They are intended to be consistent with the requirements of the final regulations (August 2020).



This non-directional cycle represents how it should all come together to improve services. This represents a continuing sequence of stages, tasks, or events in a circular flow. Each shape has the same level of importance. A provider would want the systemic risk assessment, including care concerns, to influence the risk management plan. The risk management plan may require you to conduct a root cause analysis as to why adverse incidents occur and/or what systemic issues need to be addressed. The results of your root cause analysis could lead to all kinds of quality improvement or performance improvement initiatives or goals for your quality improvement plan. And it is a continuous process as new risks and new opportunities for improvement are identified.

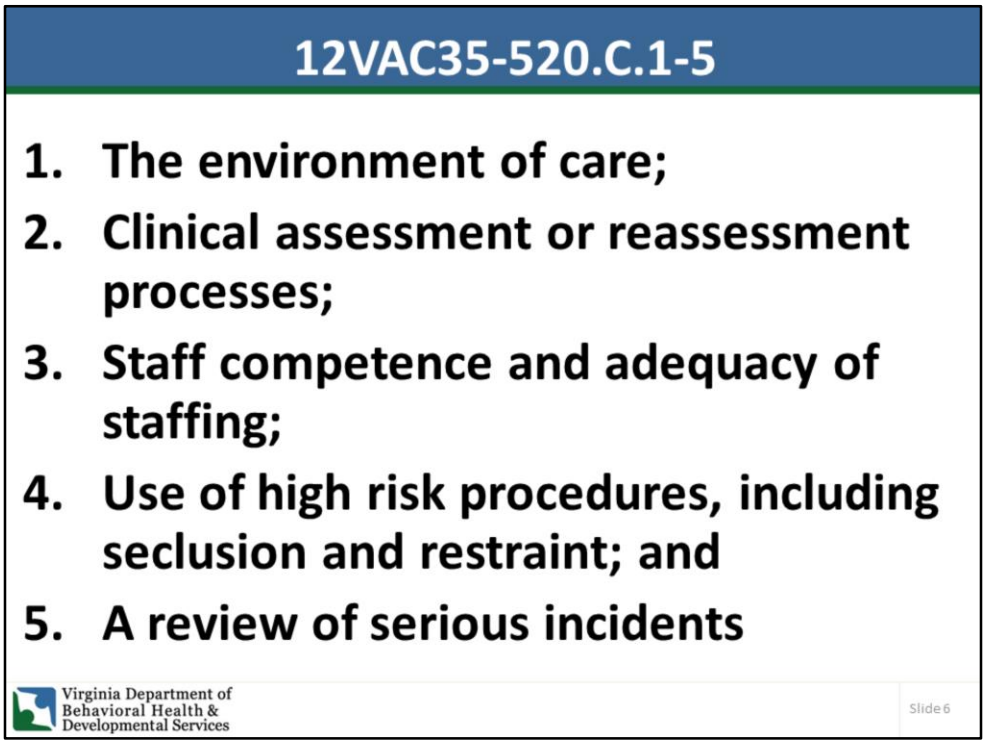
Providers are encouraged to start with the regulations.

12VAC35-105-520.C

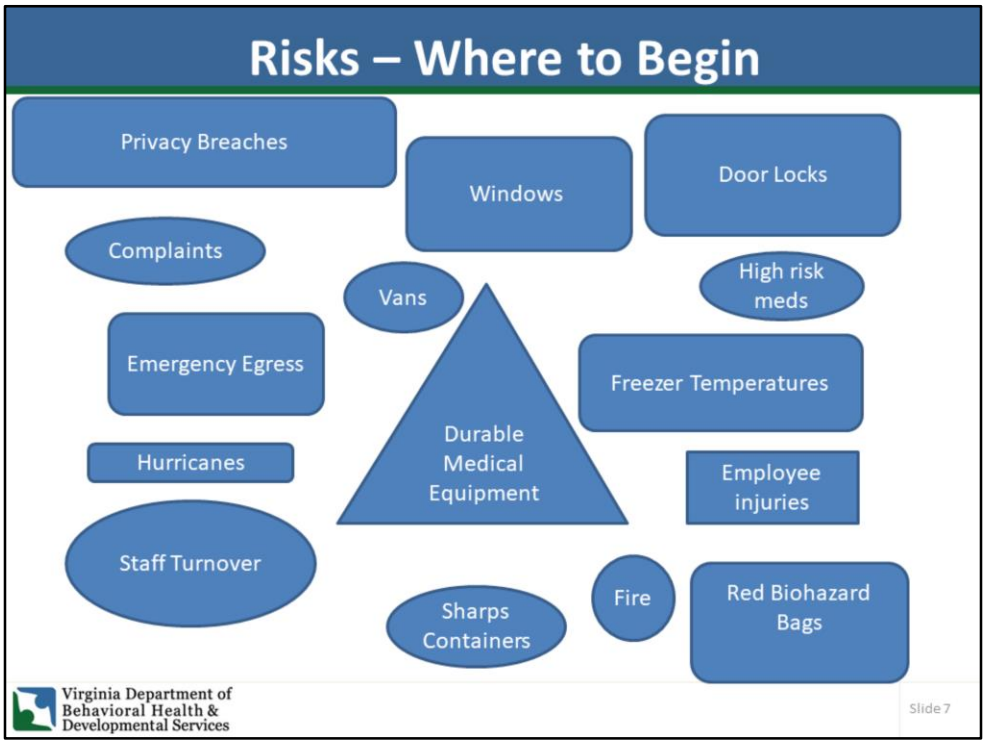
" The provider shall conduct systemic risk assessment reviews at least annually to identify and respond to practices, situations and policies that could result in the risk of harm to individuals receiving services. The risk assessment review shall address at least the following:"

Virginia Department of Behavioral Health & Developmental Services

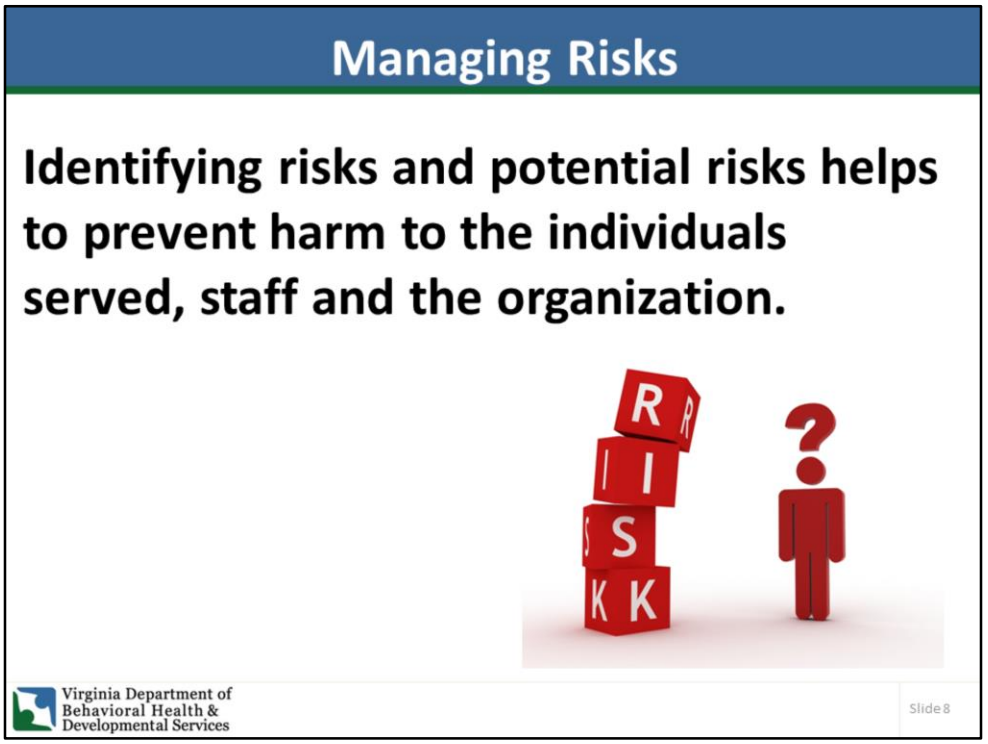
Slide 5



Please remember that the final DOJ regulations were effective August 2020 (with a grace period until November 2020 so providers had time to train and implement). Documents (related to quality improvement or risk management) posted on the DBHDS website prior to that time may not completely reflect requirements of the current regulations. So it is important to reference current regulations, and Guidance documents related to quality improvement and risk management on the Office of Licensing webpage.



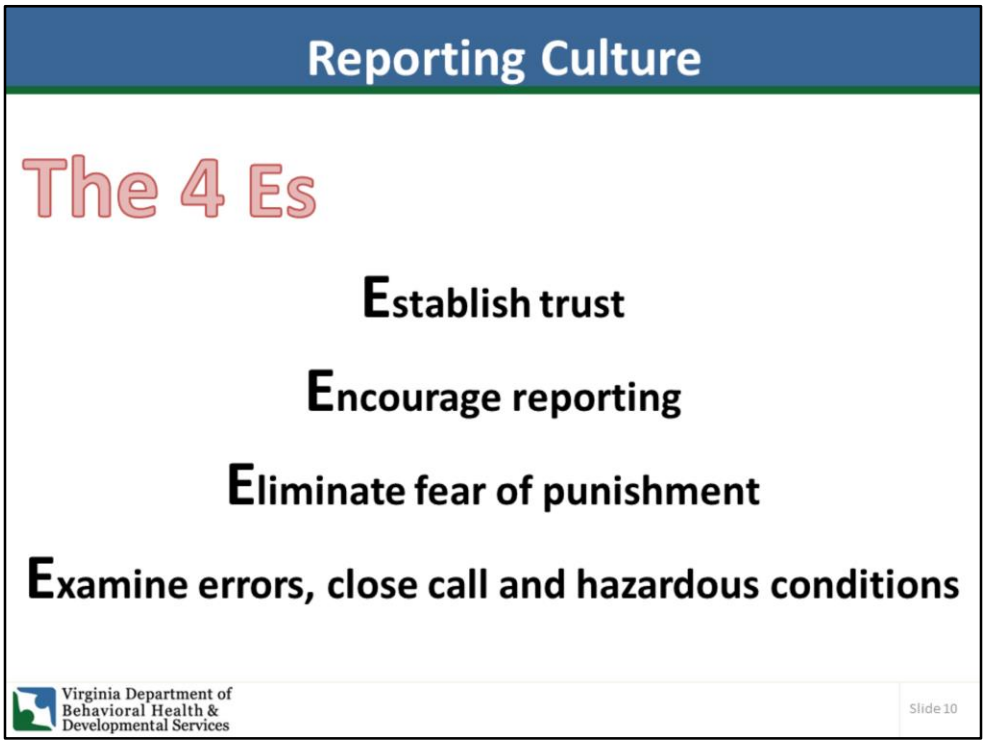
Risks are everywhere and come in many shapes and sizes. Every provider's risk assessment will therefore be different depending on the services provided, the physical location, the provider's size, as well as other factors. For example, some providers may not have sharps containers or durable medical equipment, but almost all providers have risks related to security and privacy breaches or staff turnover.



Managing risks is a way to reduce or avoid harm but first you have to identify the risks.

Providers are encouraged to think of risk identification as an opportunity; not a negative. As noted in previous slides, risks are every where. So health care organizations should encourage reporting and transparency.
It is not possible to eliminate all risks, but steps can occur to reduce or manage the likelihood or severity of an adverse outcome. For example, a provider may place a fall mat near a bed. While a fall from a bed may still occur, the injury sustained could be less severe.

Security or HIPAA breaches could occur but the risks could be minimized if the provider has processes and procedures in place to attempt to mitigate those risks.



The Joint Commission (which accredits hospitals) refers to the 4Es of A Reporting Culture (Establish trust; Encourage reporting; Eliminate fear of punishment; Examine Errors, close calls and hazardous conditions).

What is a Risk Assessment?

Is it a list of tasks for the risk manager?

Is it copying the regulations into your policy and then filing it?

Virginia Department of Behavioral Health & Developmental Services

Slide 11

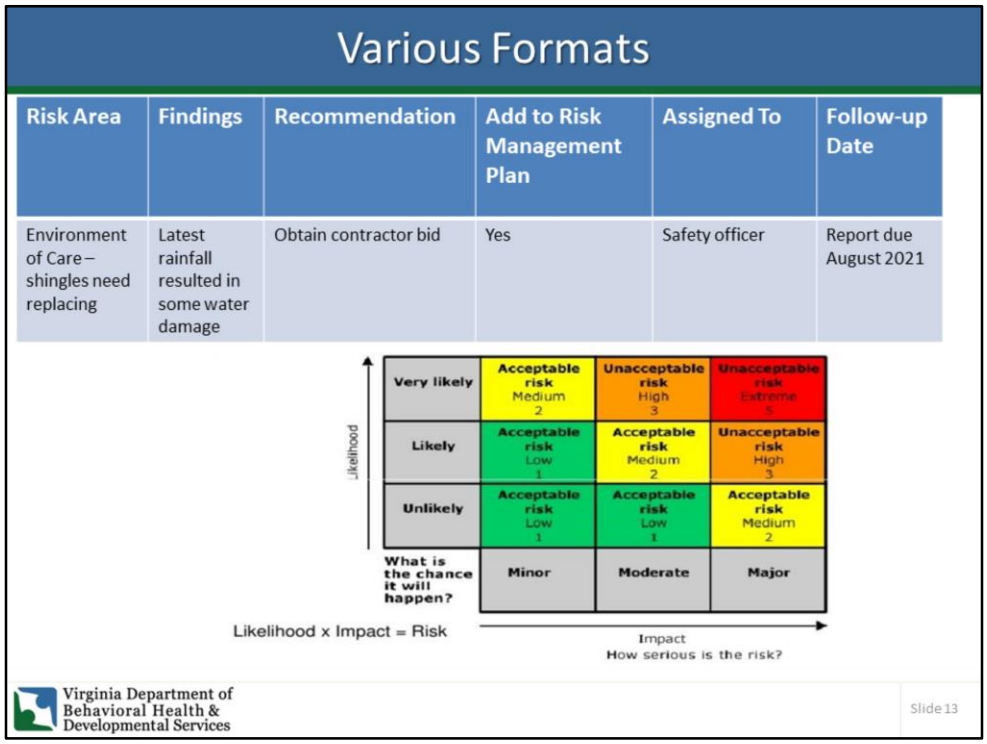
A systemic risk assessment isn't just putting the language from 520.C in a policy.

What is a Systemic Risk Assessment?

A tool for proactively identifying systemic risks before adverse events occur

Where to begin:

1. Determine a format
2. Determine who will conduct the risk assessment (leadership, risk manager, committee)

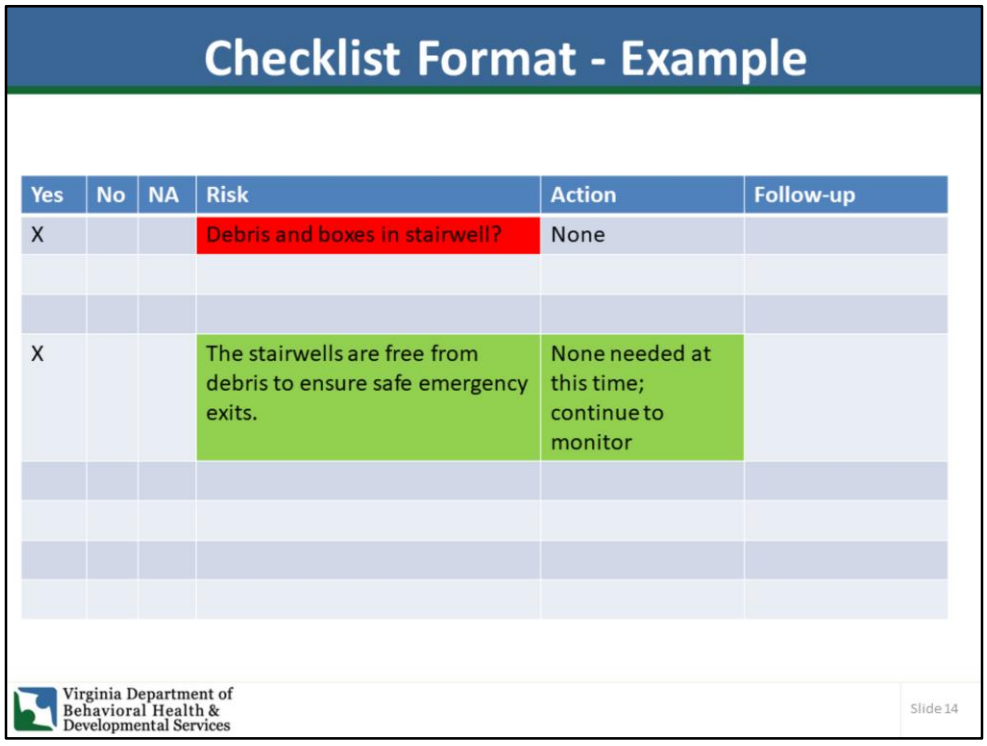


It is the provider's decision as to how to create a systemic risk assessment. Providers may go online and a search would provide lots of examples.

A provider may utilize spreadsheet with various categories that would depend of the provider's size or a risk matrix (shown at the bottom of the slide). In a risk matrix example, the provider would rank how likely something is to occur and the potential impact which would equal the risk level (example, something that has moderate impact but is very likely to occur, would be scored as an unacceptable risk (high – 3). Attention to this identified risk would take priority over something that scored a 1 (acceptable risk - low).

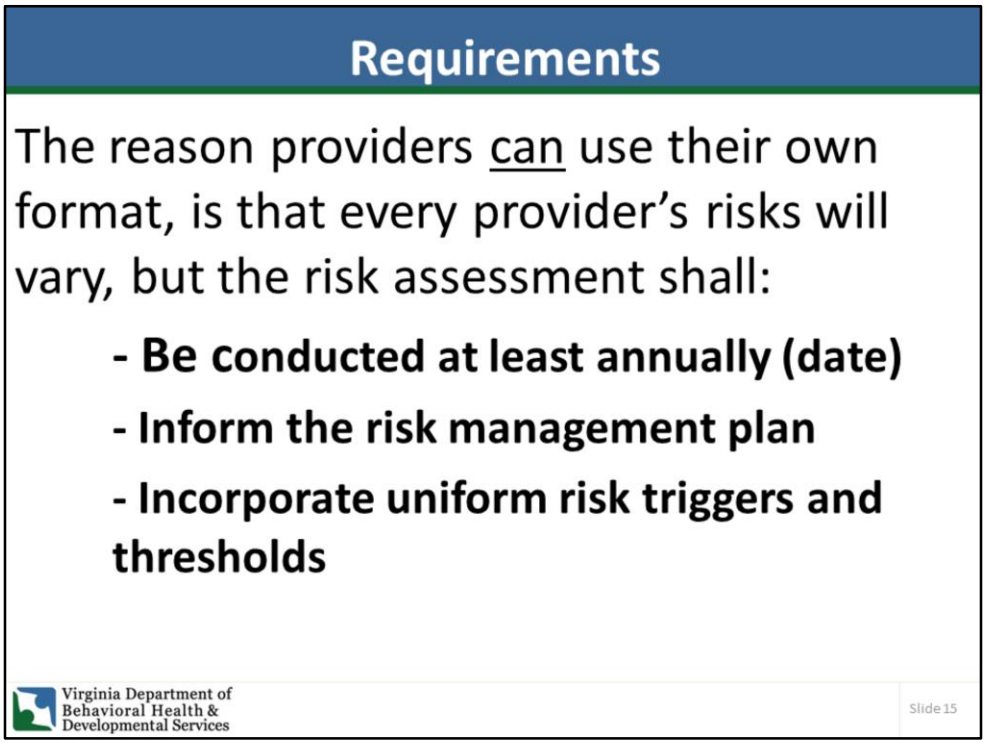
You are proactively identifying risks –
What can go wrong?

- How likely?
- How serious
- Prioritize



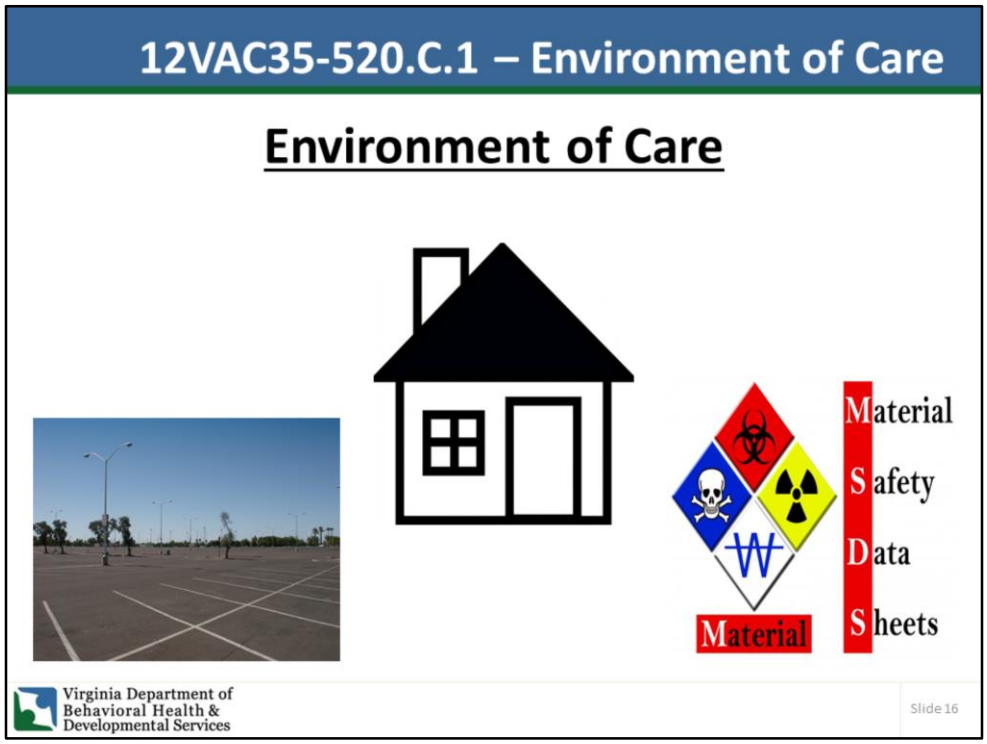
Another provider may choose a checklist format. The caution with a checklist is to make sure the individual and/or committee completing the checklist is clear about the process. In the first example (in red), the person completing the risk assessment checks "yes" meaning they checked the stairwells for boxes and debris. Does the checked "yes" mean they checked for boxes and debris in the stairwell or there were boxes and debris in the stairway?

It may be better to list as a statement as indicated in the green example above. The stairwells are free from debris to ensure safe emergency exits. Then the provider checks “yes”.



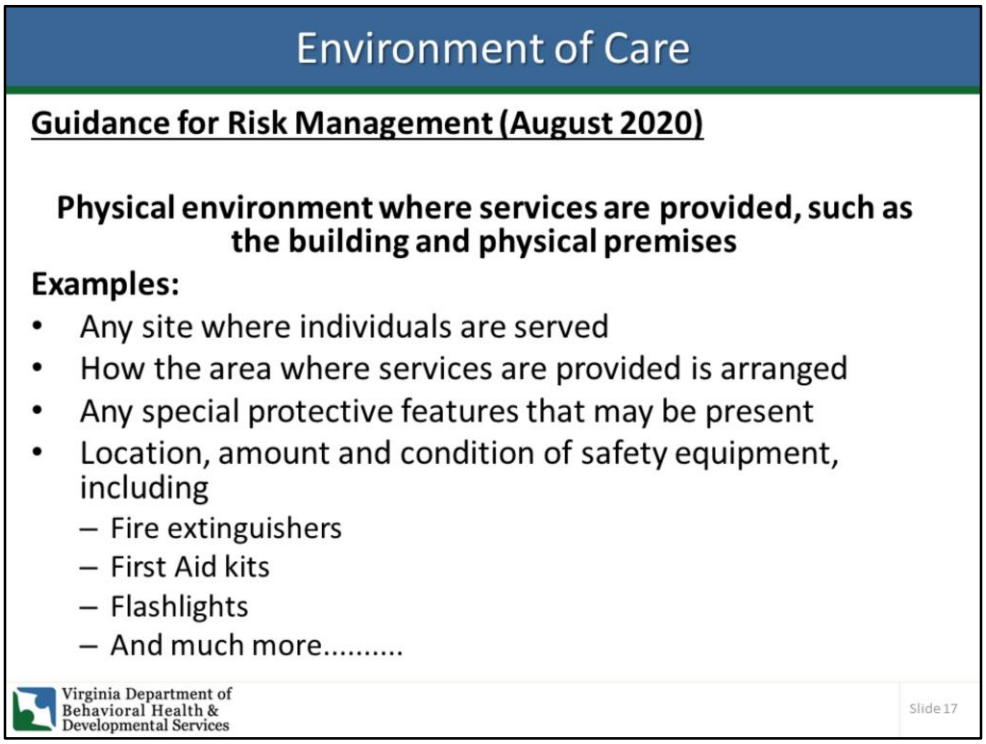
The format chosen by the provider will vary and the risks identified will vary depending on the population served, the location, the size and a host of other factors. However, all systemic risk assessments shall:

- be conducted at least annually (date risk assessment);
- inform the risk management plan (what are the priority items to address) and
- incorporate uniform risk triggers and thresholds (defined by DBHDS as care concerns).



Returning to the regulations, the systemic risk assessment shall include at least the following:

Environment of Care – what does that mean? Again, every organization will have different risks associated with its environment of care. It will depend on the location, the building (or buildings). Each provider needs to think about its environment of care and the potential risks.



Plese reference the Guidance for Risk Management which provides examples for what is included in the environment of care.

The objective is to provide a safe, functional and effective environment for individuals served, staff members and others.

Safety Inspection

How is the environment of care risk assessment different than the annual safety inspection?

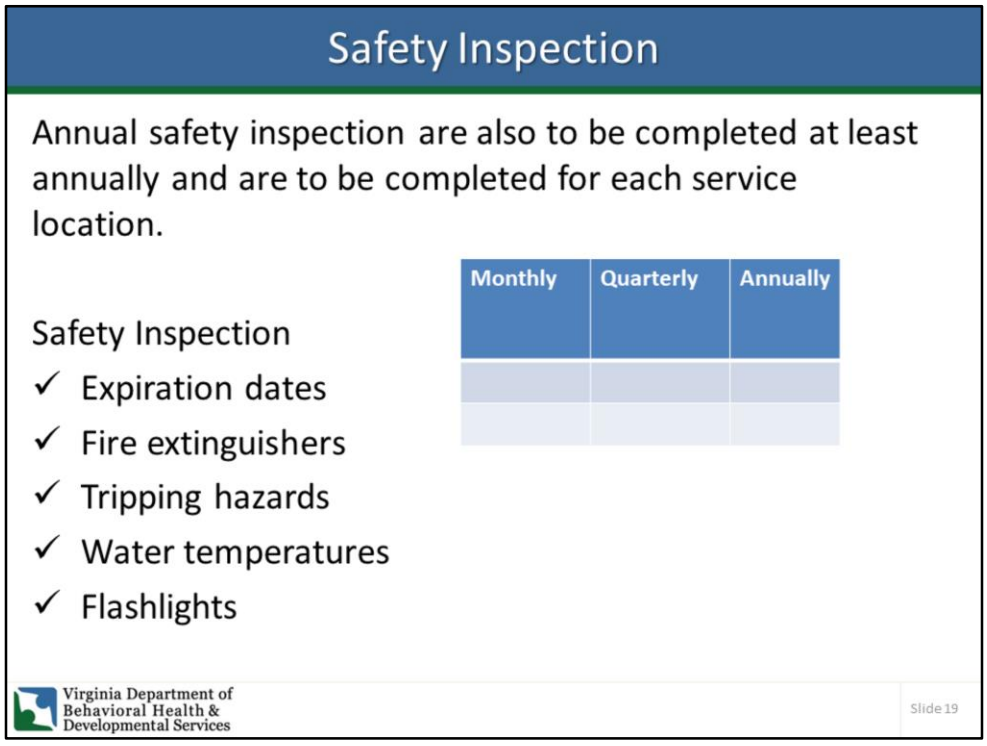
Guidance:

"A review of the environment of care should consider the results of the annual safety inspection (12VAC35-105-520.E), when applicable, but is broader than a safety inspection."

Virginia Department of Behavioral Health & Developmental Services

Slide 18

In a safety inspection, you may be checking refrigerator temperatures or sharps containers but in your environment of care you look much more broadly.



The safety inspection might be administered throughout the year as some items may be inspected monthly, quarterly, or annually. The results of these safety inspections would be considered in your systemic risk assessment.

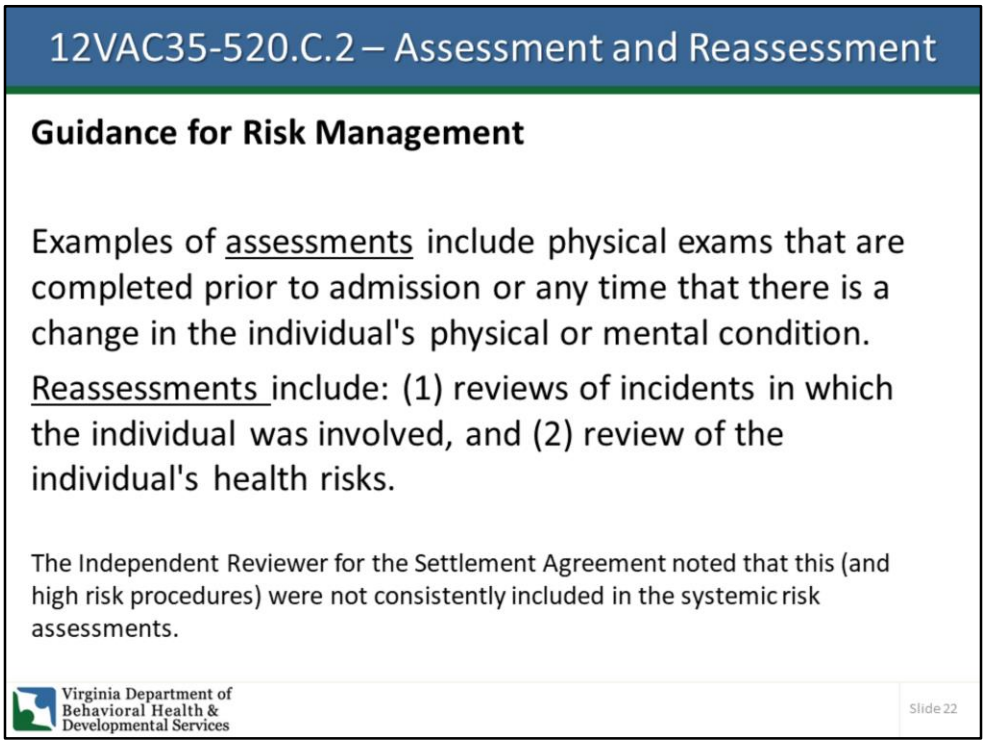
Documentation

The regulations specify a systemic risk assessment which includes the environment of care and a safety inspection (12VAC35-105-520.E)

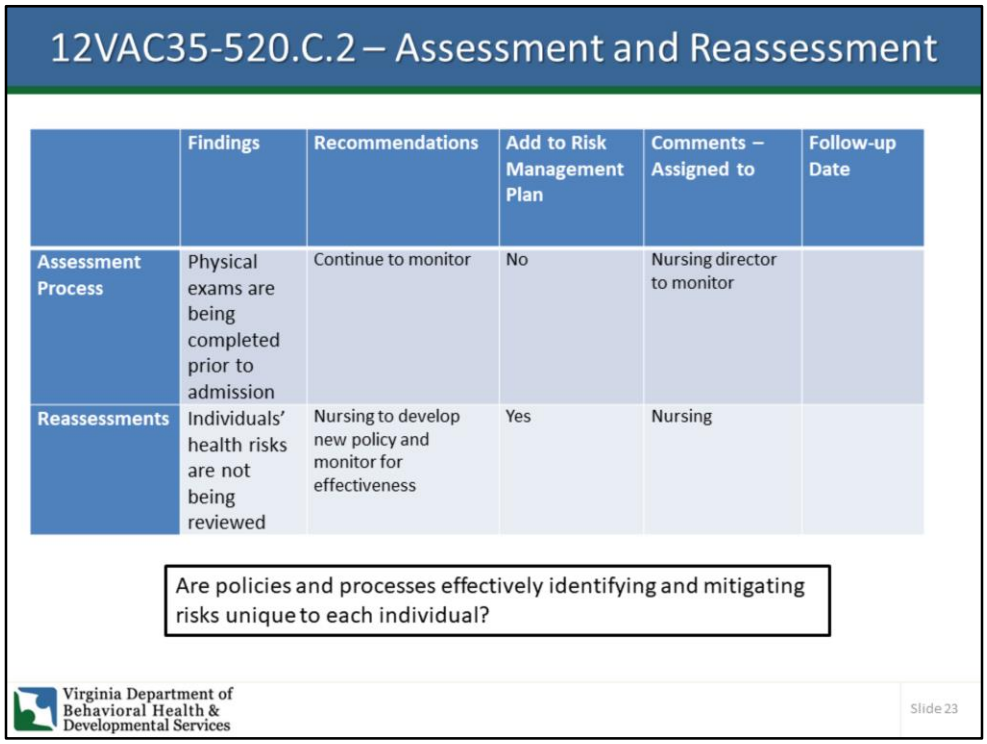
Licensing specialists conducting an annual inspection would be asking for both of these documents.

Environment of Care

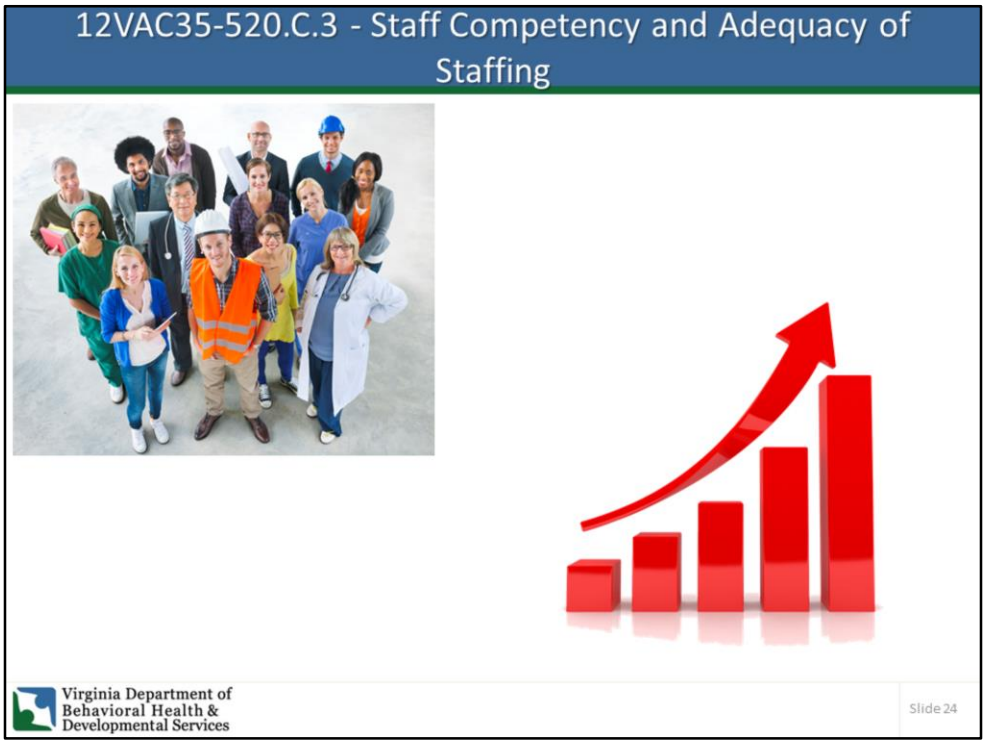
	Findings	Recommendations	Add to Risk Management Plan	Comments – Assigned to Department/Staff	Date completed; status report
Emergency egress	Building exits had boxes/trash	Staff training recommended	No	Assigned to Human Resources; report on status by (insert date)	
Ventilation	Age of building presents risks	Contract with consultant to evaluate	Yes	Assigned to building manager to request bids	Added to RM plan; bids requested (insert date)



12VAC35-520.C.2 relates to assessments and reassessments.



As noted in the Guidance for Risk Management, the person designated as responsible for the risk management function need not engage in the clinical assessment or reassessment process, but should review these processes when completing the systemic risk assessment.



People are a critical part of healthcare. Staff competency is about whether employees are trained and able to demonstrate competency. If your staff turnover rate looks like this red graph, that could be a risk in terms of developing a stable competent workforce. The risk could relate to the inability to hire and retain staff.

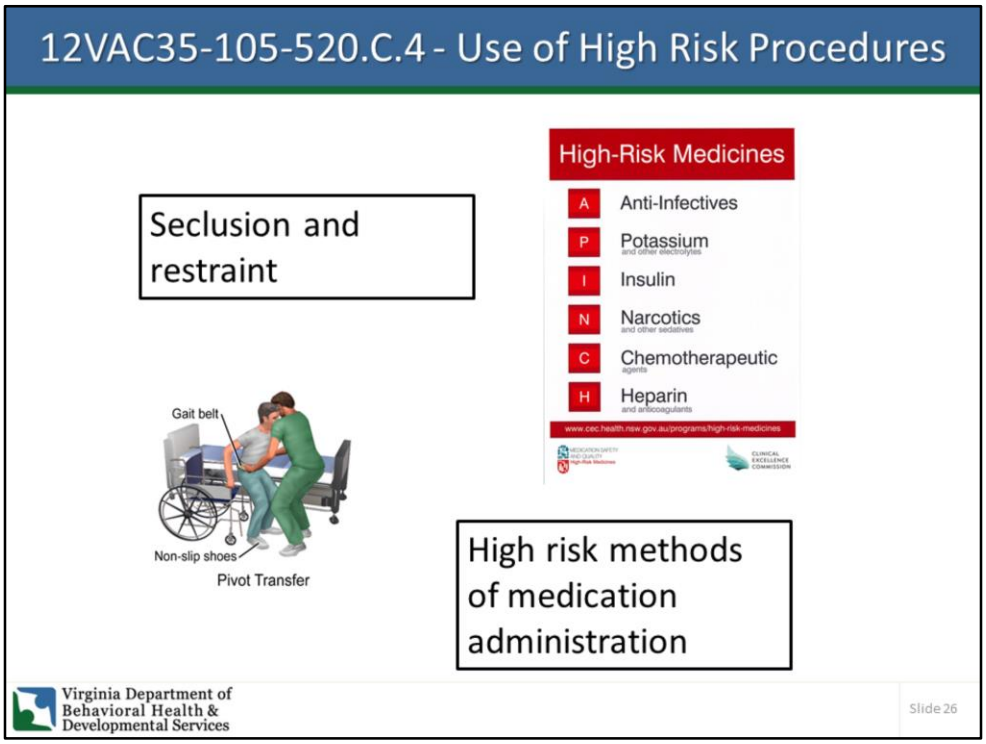
It also includes whether staffing schedules are consistent with the provider's staffing plan.

Staff Competency and Adequacy of Staffing

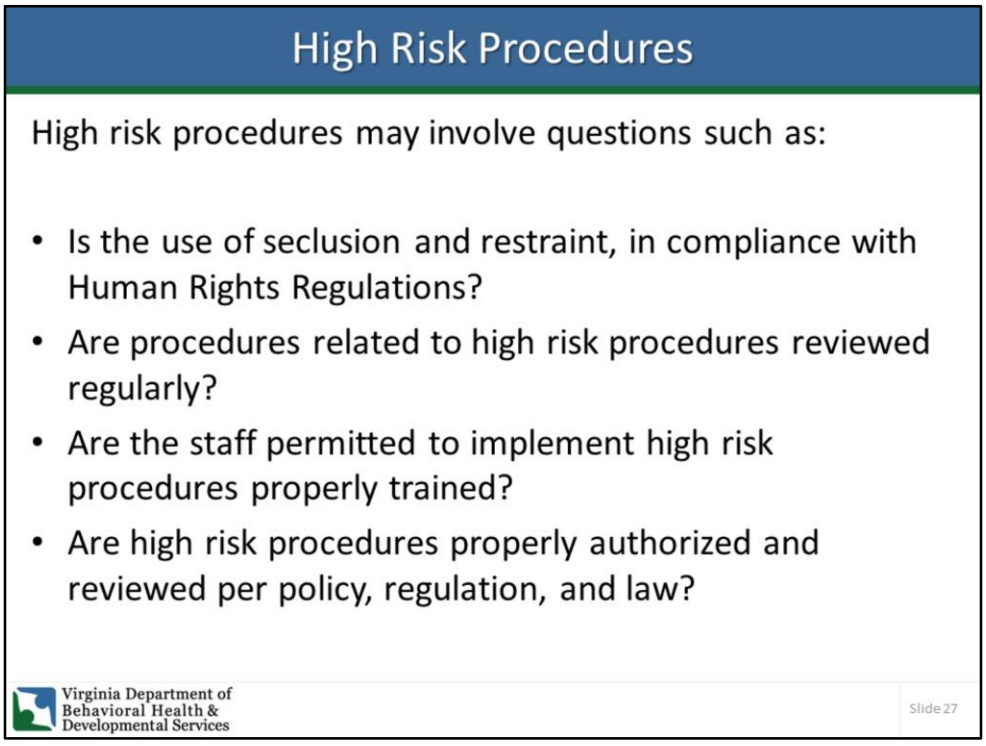
Risks vary according to the licensed provider:

- ✓ Inability to hire staff
- ✓ CPR certifications
- ✓ Background checks
- ✓ Training
- ✓ Evaluations
- ✓ Staff injuries
- ✓ Turnover rates

What are your risks – how will you seek to mitigate?

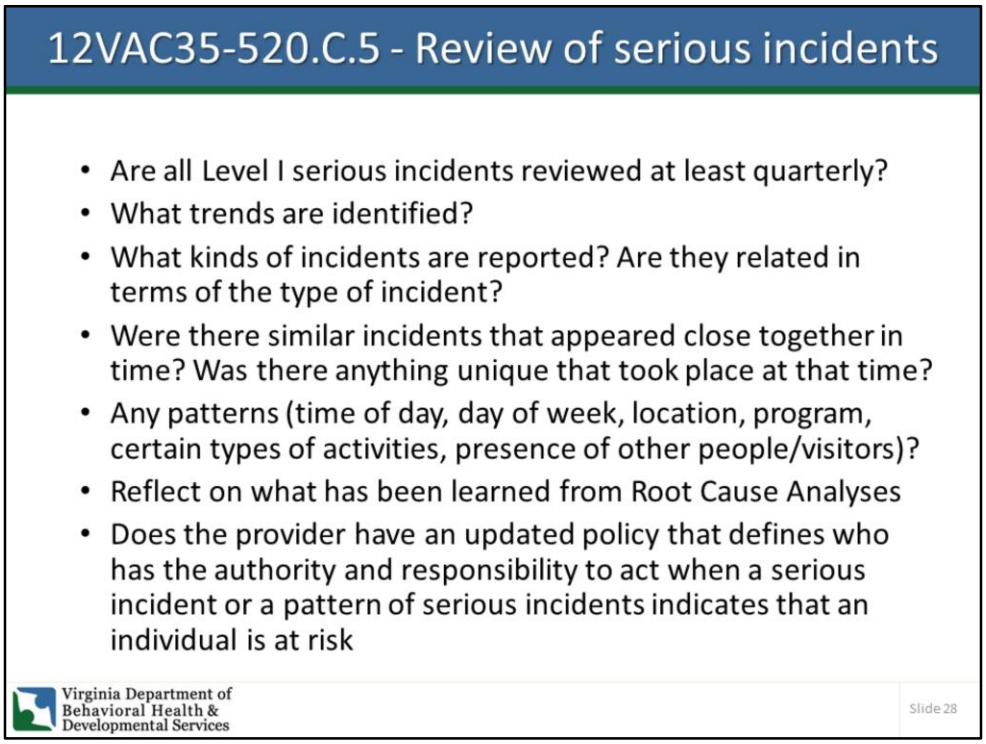


Each organization has different high risk procedures depending on the size of the organization, the services provided, and the population served.



If the organization uses high risk procedures, this should be reviewed by asking some of these questions.

When high risk procedures result in a serious incident, is the provider looking for systemic issues through a thorough root cause analysis?



The Guidance for Risk Management provides clear direction on how the systemic risk assessment is evaluating serious incidents at least annually.

And much more!

The items highlighted are those required by regulation.

There are so many more risks that may affect your organization

- security breaches
- business risks
- financial risks
- liability risks

Virginia Department of Behavioral Health & Developmental Services

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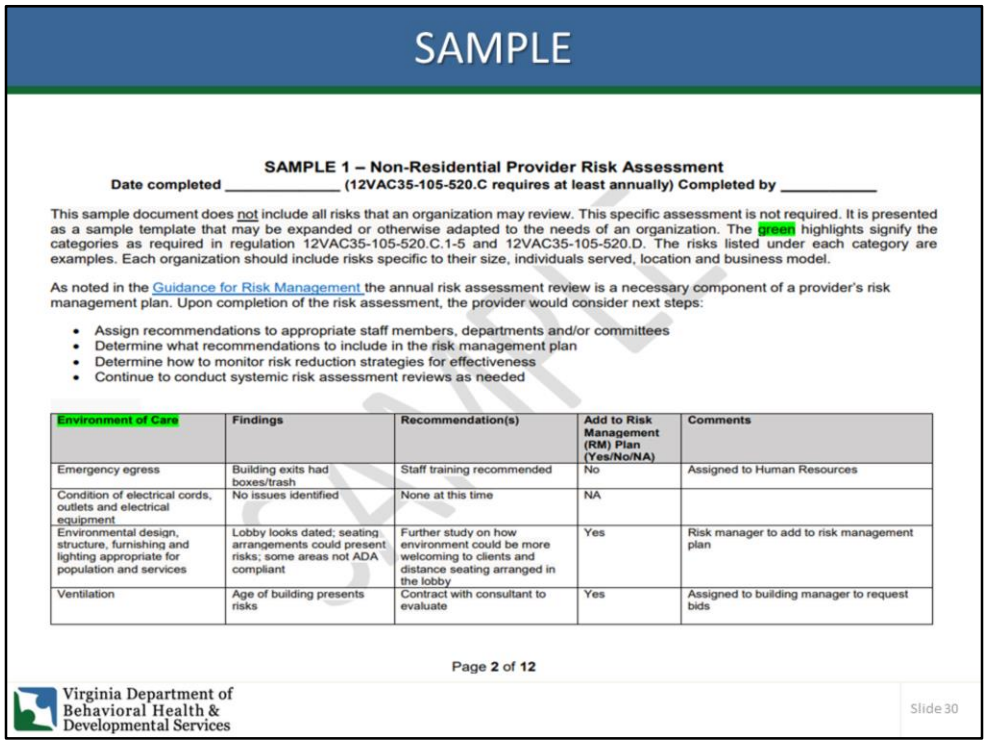
Reminder – the regulation says the risk assessment review shall address at least the following…..but don't stop there. The SAMPLE systemic risk assessment includes some additional risks that providers need to assess.

As noted in the Guidance for Risk Management, providers should consider financial risks including whether the provider has sufficient capital to support the business if revenue decrease or is delayed. Are there appropriate checks and balances over financial transactions? What workforce related risks are present?



SAMPLE

SAMPLE 1 – Non-Residential Provider Risk Assessment

Date completed _____ (12VAC35-105-520.C requires at least annually) Completed by _____

This sample document does not include all risks that an organization may review. This specific assessment is not required. It is presented as a sample template that may be expanded or otherwise adapted to the needs of an organization. The green highlights signify the categories as required in regulation 12VAC35-105-520.C.1-5 and 12VAC35-105-520.D. The risks listed under each category are examples. Each organization should include risks specific to their size, individuals served, location and business model.

As noted in the Guidance for Risk Management the annual risk assessment review is a necessary component of a provider's risk management plan. Upon completion of the risk assessment, the provider would consider next steps:

- Assign recommendations to appropriate staff members, departments and/or committees
- Determine what recommendations to include in the risk management plan
- Determine how to monitor risk reduction strategies for effectiveness
- Continue to conduct systemic risk assessment reviews as needed

Environment of Care	Findings	Recommendation(s)	Add to Risk Management (RM) Plan (Yes/No/NA)	Comments
Emergency egress	Building exits had boxes/trash	Staff training recommended	No	Assigned to Human Resources
Condition of electrical cords, outlets and electrical equipment	No issues identified	None at this time	NA	
Environmental design, structure, furnishing and lighting appropriate for population and services	Lobby looks dated; seating arrangements could present risks; some areas not ADA compliant	Further study on how environment could be more welcoming to clients and distance seating arranged in the lobby	Yes	Risk manager to add to risk management plan
Ventilation	Age of building presents risks	Contract with consultant to evaluate	Yes	Assigned to building manager to request bids

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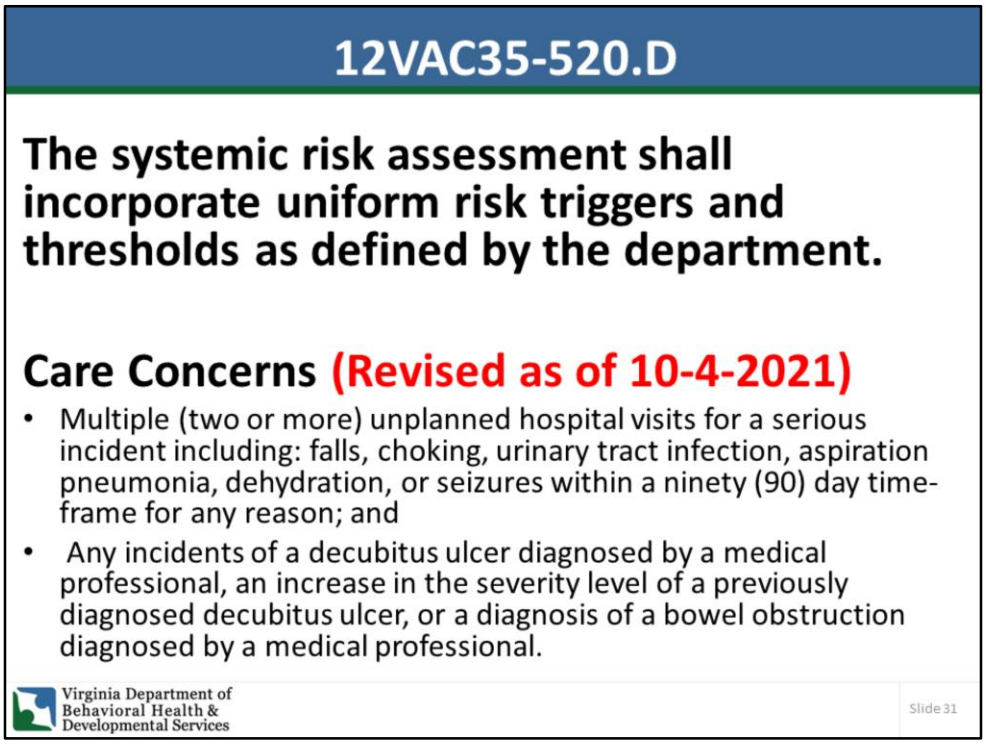
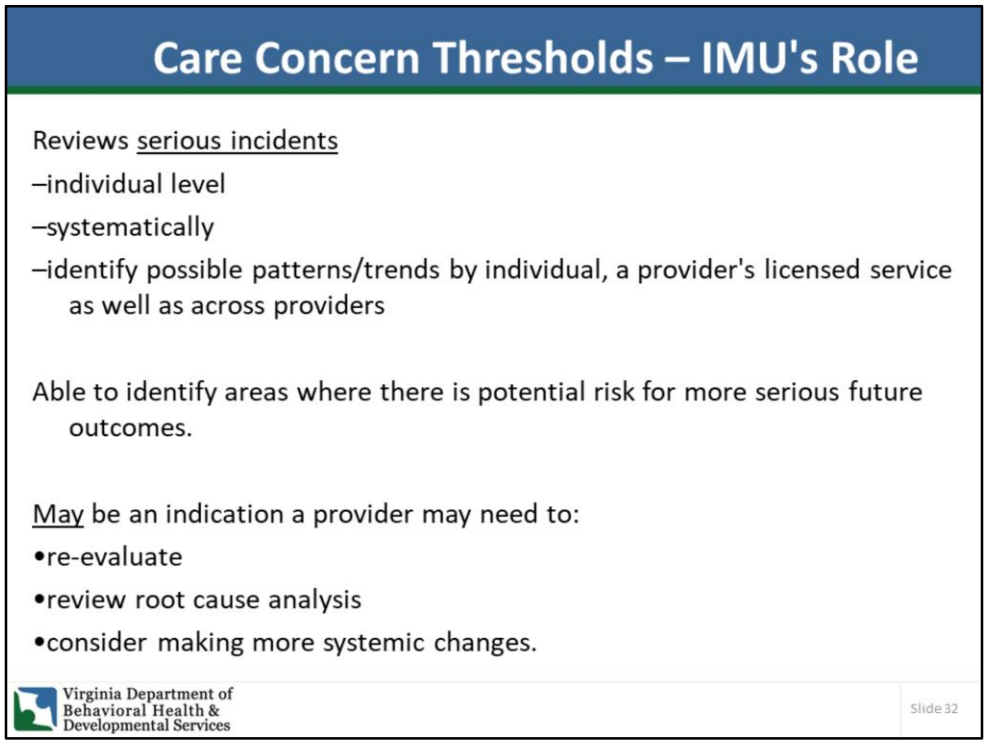
Slide 30

As noted in the SAMPLES, every organization's systemic risk assessment will look different depending on the services provided, population served, etc.



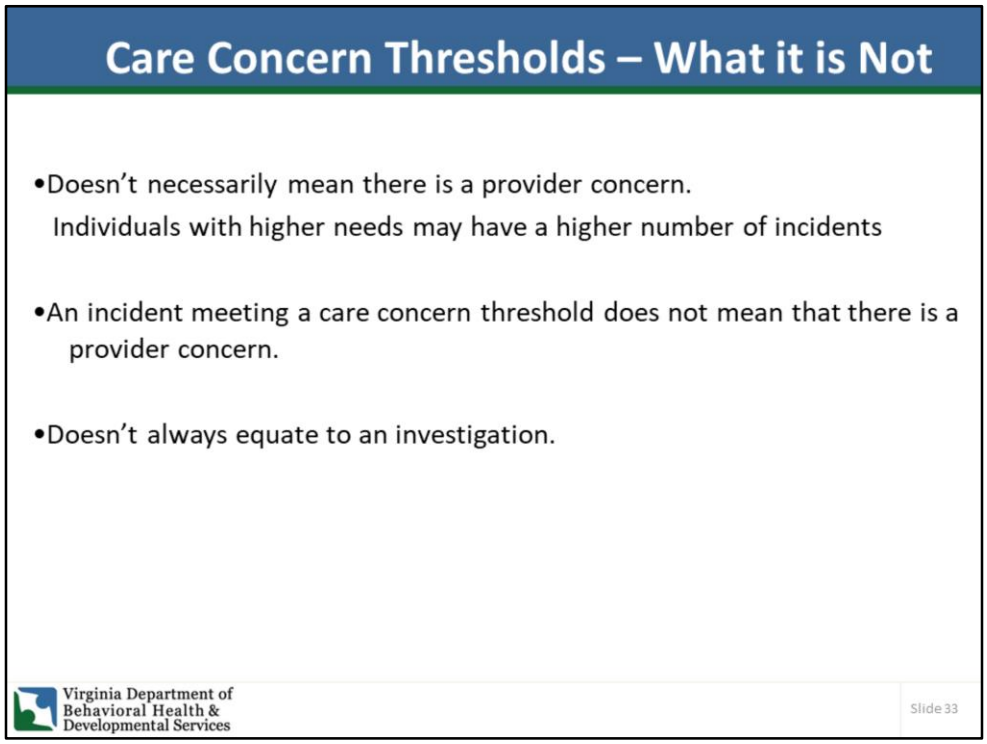
The DBHDS Incident Management Unit (IMU) will triage any incidents that fall into these two care concern categories to the Office of Human Rights (OHR) and/or Office of Integrated Health (OIH) for review and follow up. Incident reports designated as care concerns will only be triaged to the assigned Licensing Specialist for investigation if the IMU determines from a review of the incident report that individuals served may be at an imminent risk of harm or if there are any outstanding regulatory concerns after the OHR/OIH review is complete.



The IMU reviews serious incidents not only on an individual level but systematically as well to identify possible patterns/trends by individuals, a provider's licensed service, and across providers.

Through this review, the IMU is able to identify areas, based on serious incidents, where there is potential risk for more serious future outcomes.

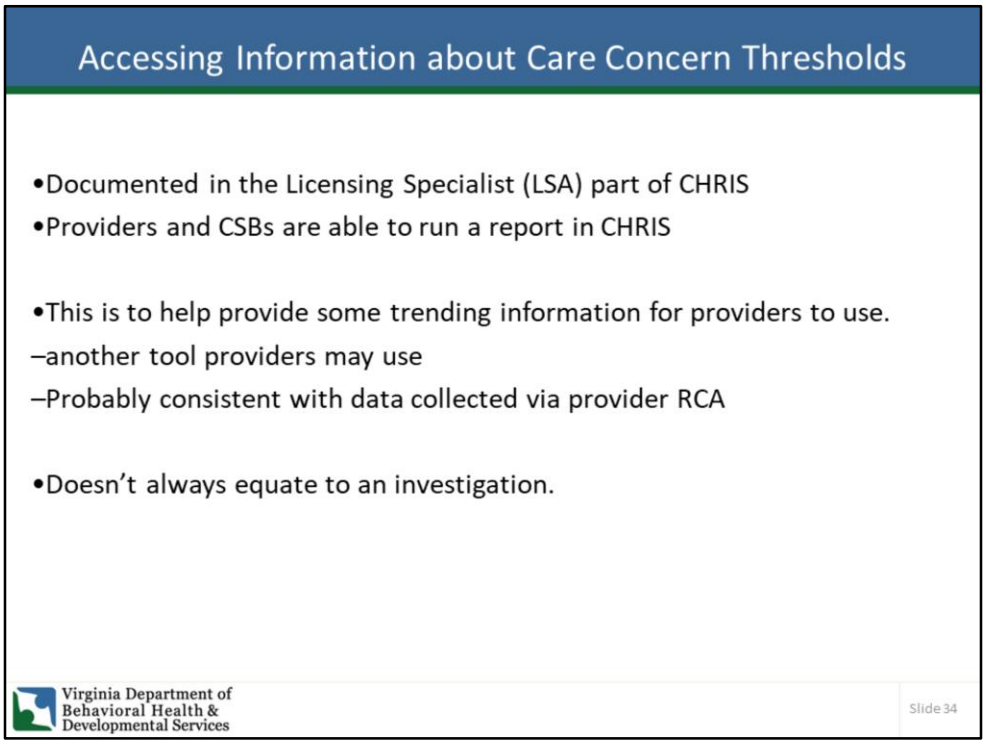
When care concerns thresholds are met it may be an indication a provider may need to re-evaluate an individual's needs and supports, review the results of their root cause analysis or even consider making more systemic changes.



Now we realize that providers who support individuals with higher needs may have a higher number of incidents just because and individual may be at higher risks for incidents/injuries that may result in events such as medical or psychiatric hospitalizations.

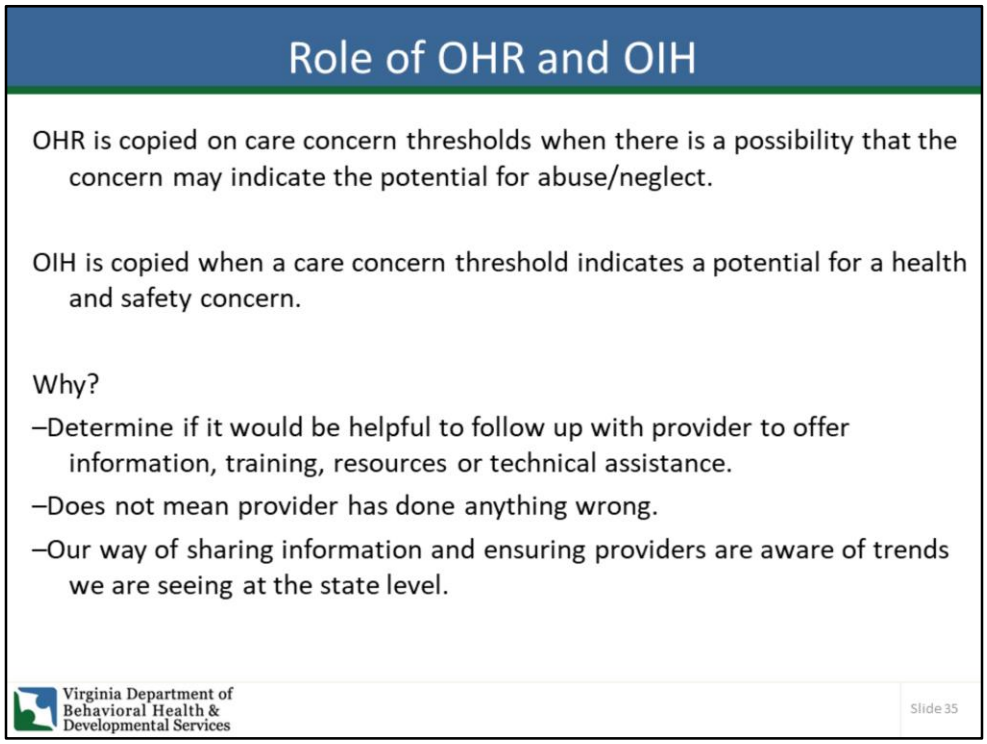
So just because an incident meets a care concern threshold does not mean that there is concern a provider is not doing what they are supposed to be doing.

There are times when a care concern may also become a general concern for the OL and then the concern is passed along to a specialist to determine if there is a need to open an investigation but this is not necessarily the case.



We share the information with providers via putting information into the LSA part of CHRIS and also providers are able to run a report in CHRIs to see which individuals have met care concerns. This is to help provide some trending information for providers to use.

This is just another tool providers may use to assess if an individual is getting the supports they need or if there may be a need to be some changes on an individual or a provider level.
very likely may mirror when a provider has determined to conduct a more detailed RCA in accordance with our regulations and their own RCA policy



The OHR is copied on care concerns when there is a possibility that the concern may indicate the potential for abuse/neglect. The OHR will assess if there is a need to follow-up to get more information or to provide TA.

The same thing occurs when an care concerns indicates a potential for a health and safety concern. The IMU is copied on the care concern and the OIH assesses the need to follow up with provider to offer information, training, resources or technical assistance.

Having OHR or OIH contact you about a care concern, again, does not mean you have done something wrong. It is our internal way of sharing information and ensuring providers are aware of trends we are seeing at the state. Please remember we have new providers, old providers, frequently changing provider staff and we want to make sure we can share information with you all as appropriate.

Care Concern Threshold

Providers should have an established protocol on how to handle Care Concerns identified by DBHDS.

The protocol could include:

–Complete Root Cause Analyses (RCA)

–Review Previous Incidents

–Review the Individual's Support Plan

–Conduct Team Meeting

–Staff Retraining

–Additional Assessments

Care Concern Threshold

Example of when a Fall Care Concern Threshold has been identified:

- Complete RCA- include physical environment (review lighting, uneven floors, clutter, medications, behavior, medical status, etc)
- Review all incidents (Level I, II, III) involving the individual, identify/analyze patterns and trends or potential systemic issue
- Meet with the team to review/update ISP, identify corrective actions or preventative measures, written protocols, additional assessment, additional supports to mitigate future incidents
- Train or educate staff with new or updated supports
- Designate a person in the organization who will conduct on-going monitor, record or documentation of implementation of corrective actions and ensuring supports written in the plan are in place/performed, monitor effectiveness and reduce incidents (Need to be measurable, i.e. no falls incident within 90 days). DOCUMENT, document, and document.
- Team review of the effectiveness of the plan initially (upon plan implementation) i.e. within 3 and 6 months, then annually if no incidents, or anytime there is need or changes in the individual's status- medical, behavioral, etc.

Risk Triggers and Thresholds

What will licensing specialist be looking for?

That the provider's systemic risk assessment includes a review of risk triggers and thresholds (care concerns) that were met and how they were addressed.

What if the provider didn't have any care concerns?

The provider should include in their risk management plan how they would review/address care concerns if they do arise.

What if no changes were necessary after review of care concerns?

The provider should document why no changes were made to individual or programmatic services.

Systemic Risk Assessment

Risk assessment complete – Is the provider done?

No – the provider has identified risks

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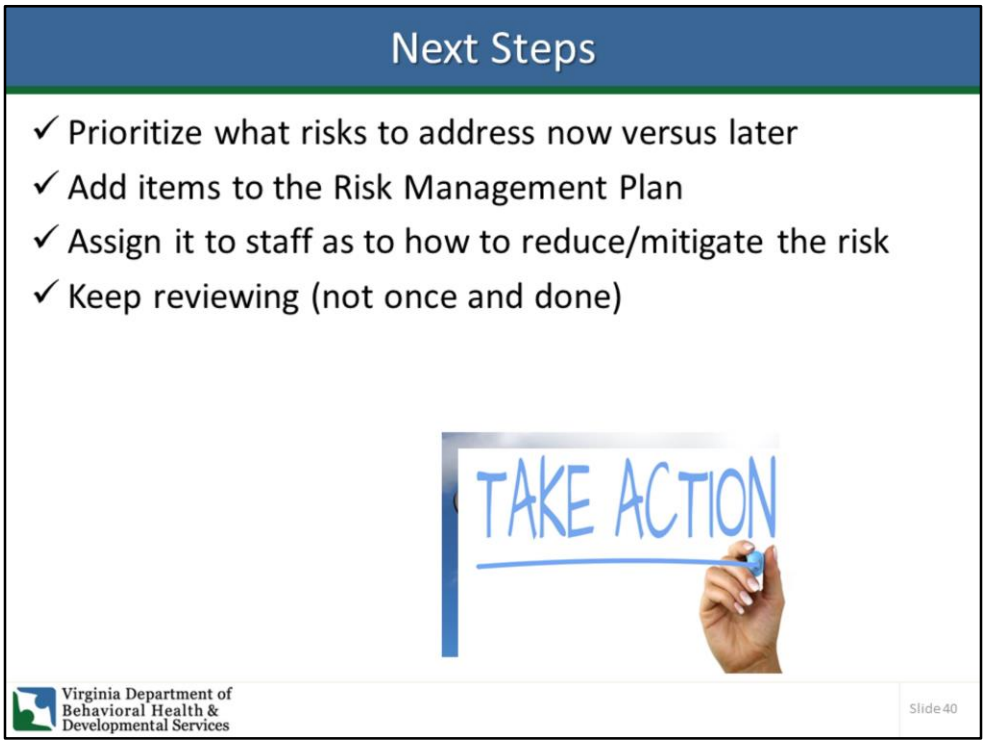
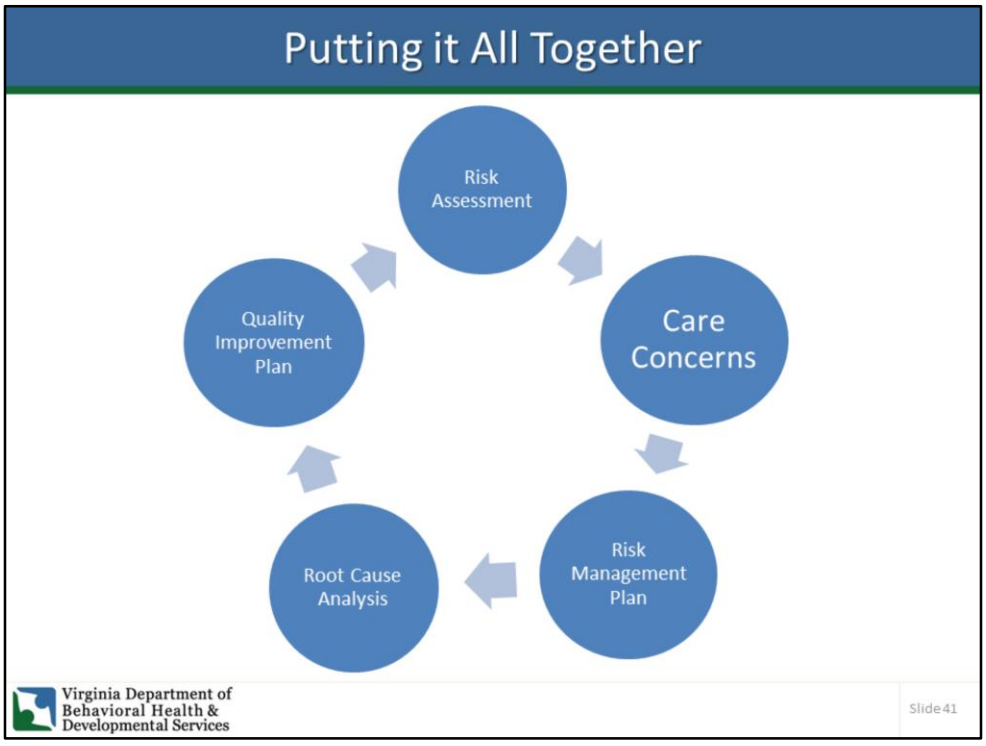
The systemic risk assessment is about identification of risks.



Once the risk assessment is completed, the provider needs to prioritize what will be addressed now versus later (focus on high volume, problem prone, high risk). Then add those items to the risk management plan or assign to staff to address through risk mitigation efforts.

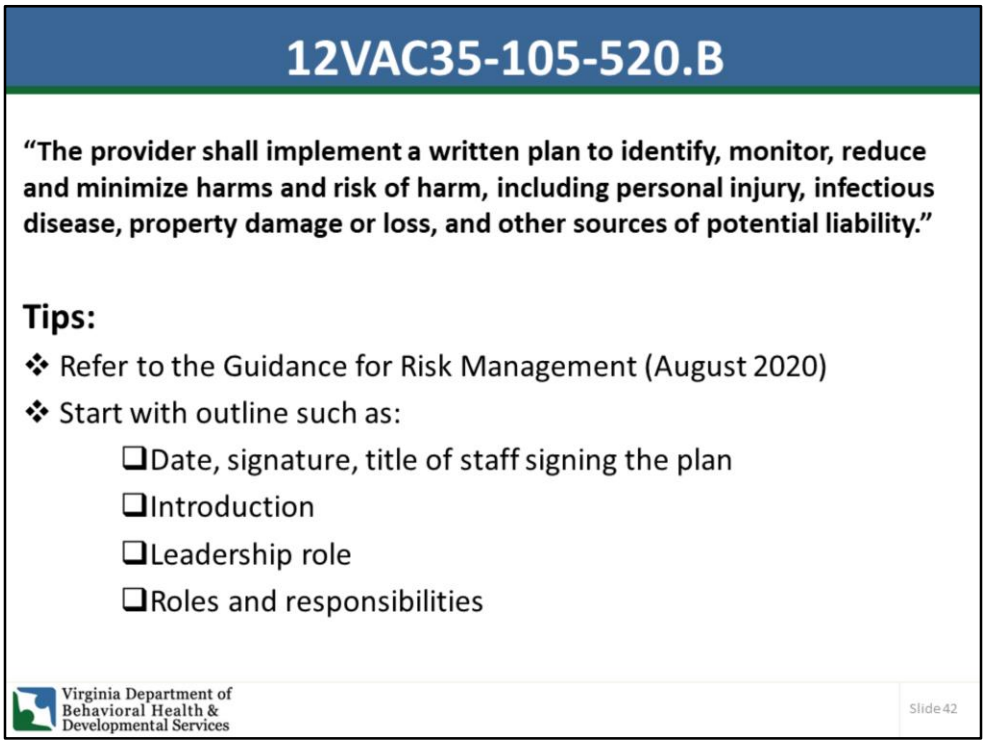
And keep reviewing. The regulations state that the systemic risk assessment is to be done at least annually so the provider may return to this more frequently as new potential risks are identified.

Most importantly, take action. This is not a document to complete and put on the shelf.

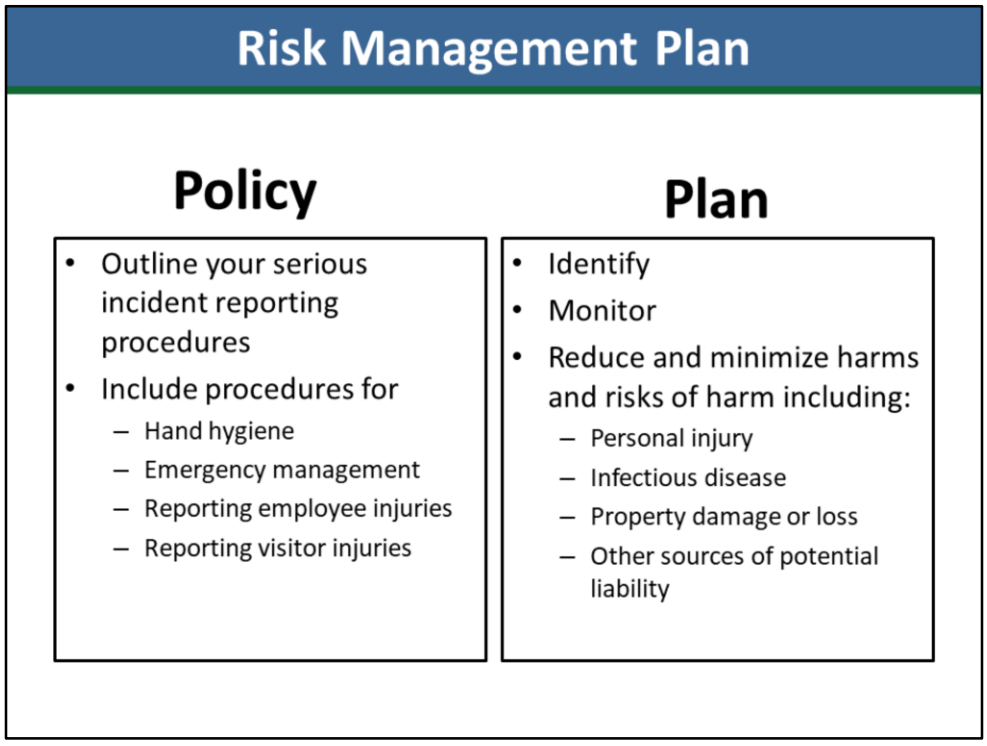


As noted earlier, this non-directional cycle represents how it should all come together to improve services.

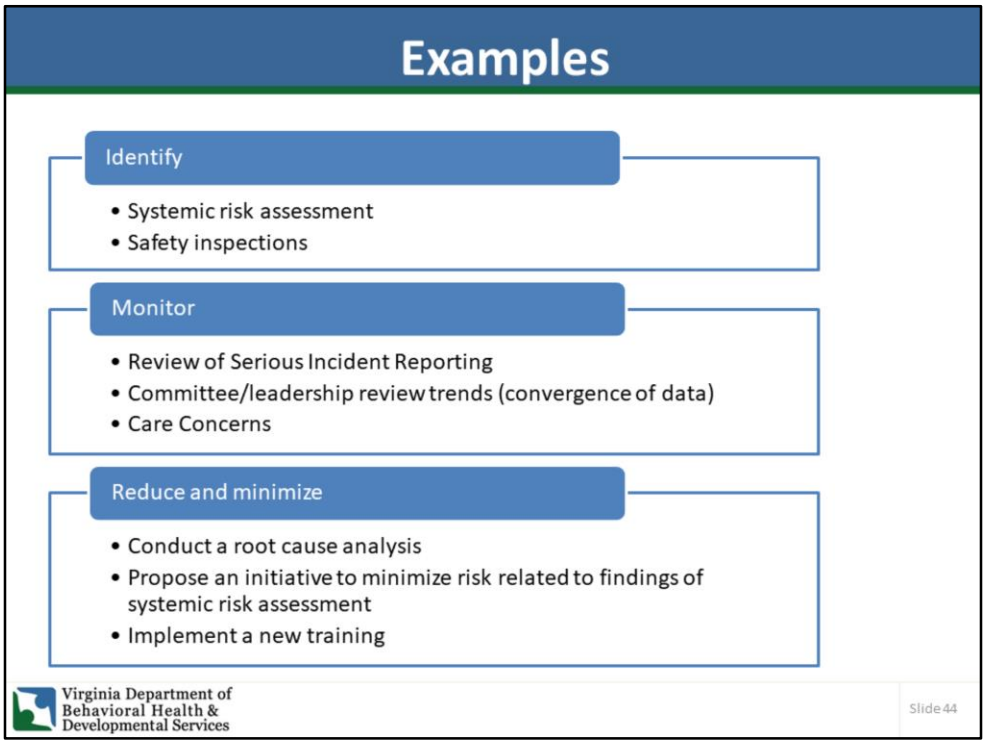
The systemic risk assessment is a necessary component of your risk management plan.



The regulations and the Guidance for Risk Management outline the requirement for a written risk management plan.



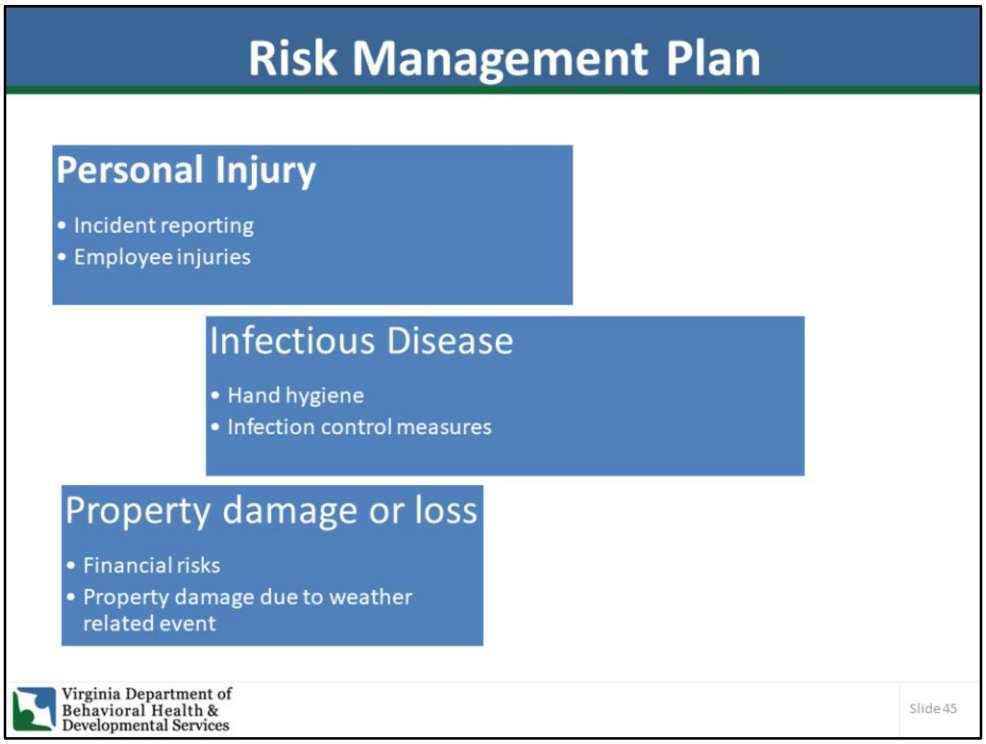
This slide is to help provider delineate between policy and a plan. A provider may have various policies related to risk management such as hand hygiene policy, universal precautions policy, emergency management procedures, a policy on reporting employee injuries, etc. Those are policies but a risk management plan is separate. A plan may be seen as a road map – where the provider is focusing efforts. What is the provider's focus related to identification, monitoring and reducing/minimizing harms and risks of harms.



In the SAMPLE risk management plan, examples are provided on how to identify, monitor, reduce and minimize.
Identification – risk assessment, safety inspection, etc.

How does a provider monitor? There may be a committee, a work group, a team that regularly reviews data and looks for trends. The convergence of data is when a provider identifies that there has been an increase in serious incidents when there has been staff turnover.

Reducing and minimizing – look at root causes, propose a quality improvement initiative or a new training



Referencing the regulations again 12VAC35-105-520.B -

The provider shall implement a written plan to identify, monitor, reduce and minimize harms and risk of harm, including personal injury, infectious disease, property damage or loss, and other sources of potential liability.

Risk Management Plan

General Tips:

- Get input from frontline staff
- Regularly share updates with staff
- Please don't put it on the shelf --
- Revisit regularly – update/revise/evaluate

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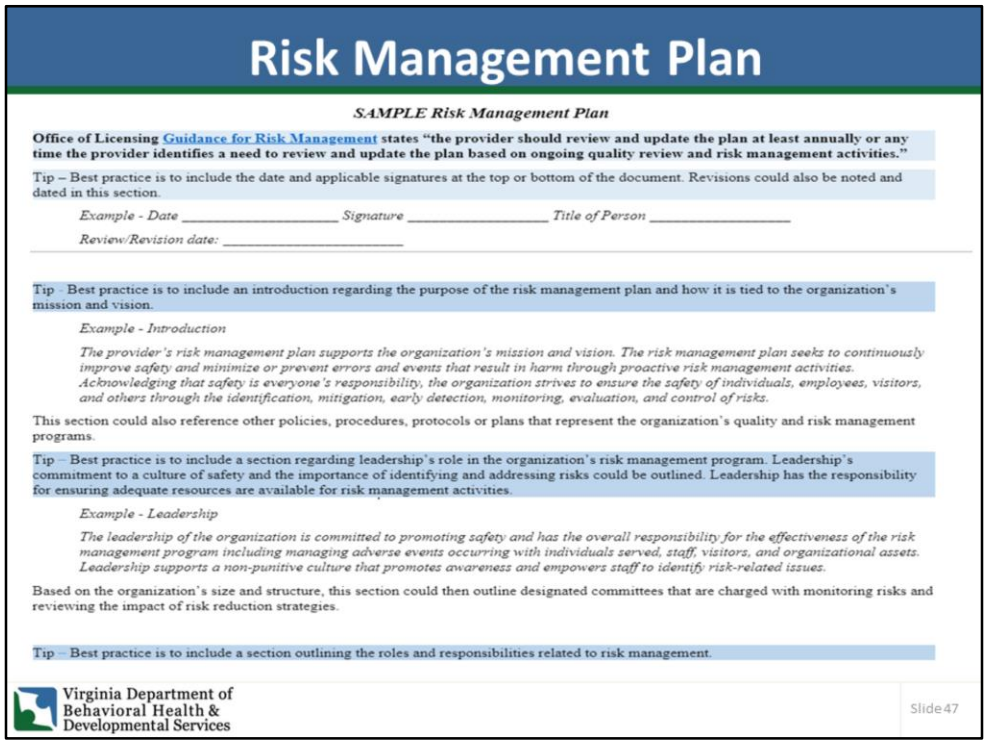
The risk management plan should involve everyone and should be reviewed regularly.



The SAMPLE risk management plan includes tips for best practice as well as reference to requirements outlined in the regulations.

Before we move on to quality improvement plans, a quick reminder. While the Office of Licensing did not issue a SAMPLE of a combined quality improvement/risk management plan, providers may choose to do so. As noted in the Guidance for Risk Management, the provider's risk management plan may be a standalone risk management plan or it may be integrated into the provider's overall quality improvement plan. Just remember to include all of the elements as required by the regulations.

12VAC35-105-620.A

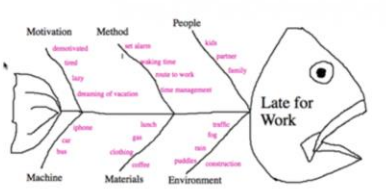
"The provider shall develop and implement written policies and procedures for a quality improvement program sufficient to identify, monitor and evaluate clinical and service quality and effectiveness on a systematic and ongoing basis."

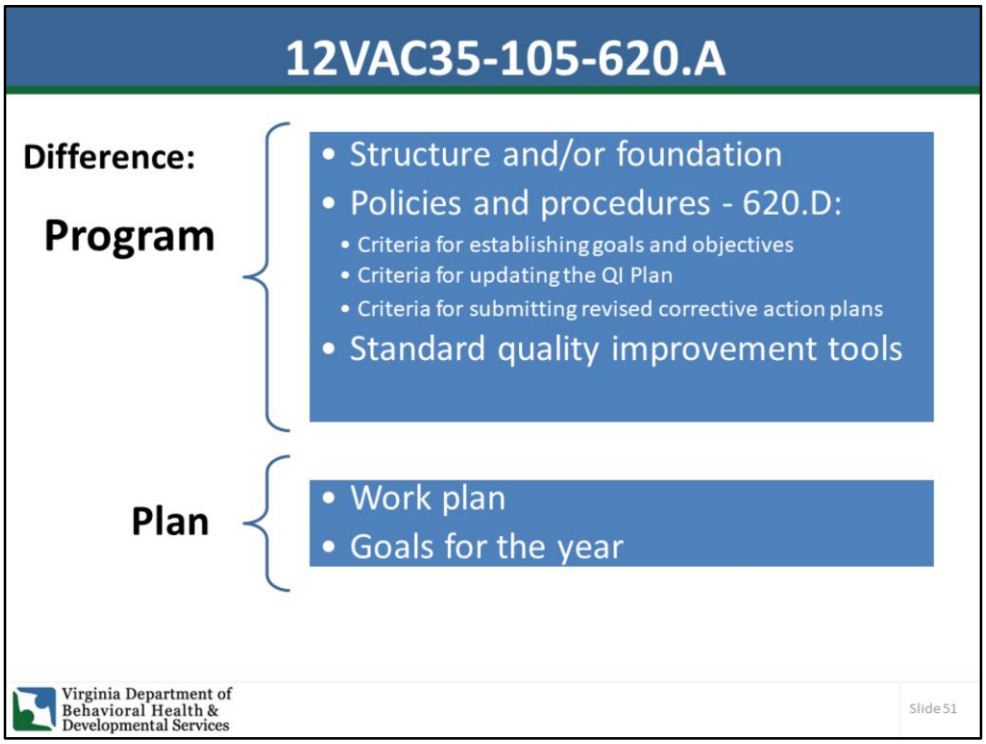
Examples:

- Quality committee(s) structure or persons assigned to monitor quality improvement efforts
- Procedures for evaluating clinical and service quality (record reviews, utilization reviews, customer satisfaction surveys)
- Serious Incident Reporting Policy
- Root Cause Analysis Policy
- Policy on actions that the provider may take to address deficiencies identified by citations and how/when Corrective Action Plans will be monitored

12VAC35-105-620.B

"The quality improvement program shall utilize standard quality improvement tools, including root cause analysis, and shall include a quality improvement plan."





The difference between a program and a plan is that the program may be outlined in policies and procedures, but the provider's quality improvement plan is the provider's plan or road map for the year.

QI Plan Definition

12VAC35-105-20 defines a quality improvement plan as a detailed work plan developed by the provider that defines steps the provider will take to review the quality of services it provides and to manage initiatives to improve quality. A quality improvement plan consists of systematic and continuous actions that lead to measurable improvement in the services, supports and health status of the individuals receiving services.

SAMPLE quality improvement plan gives tips

Best practice is to include guiding principles

Best practice would be to define terms

Examples are given of these best practices

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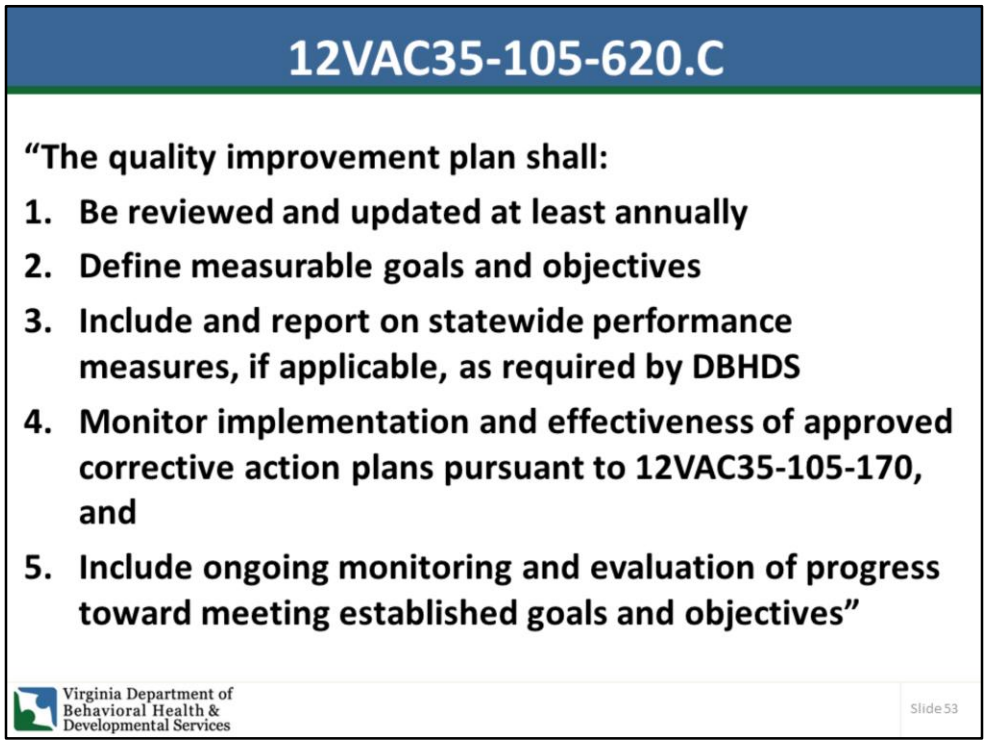
Providers are encouraged to refer to the definitions section of the regulations as to what should a quality improvement plan should include.



The SAMPLE however also references what is required by regulation. These items are required.

12VAC35-105-620.C.1

Be reviewed and updated at least annually

What will the licensing specialist be looking for?

Guidance states that the QI plan should be dated and signed to indicate when it is implemented and when any updates occur.

Providers decide on what annual means to your organization (calendar, fiscal)
"At least annually"- there may be other times a provider updates the QI plan (change in service, CAP)

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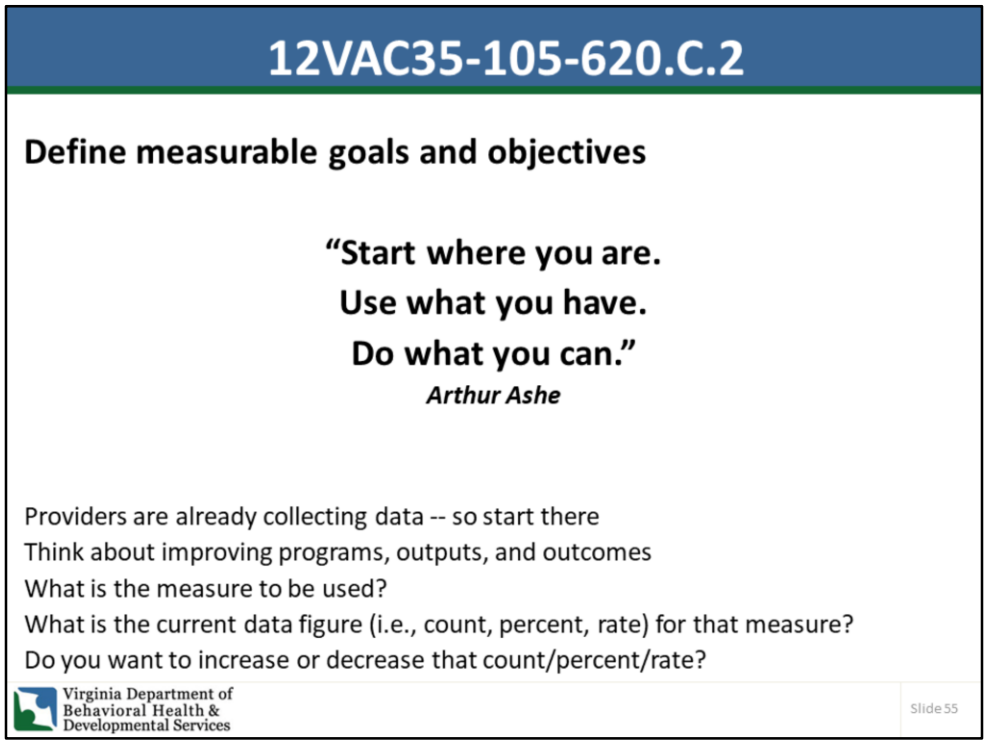
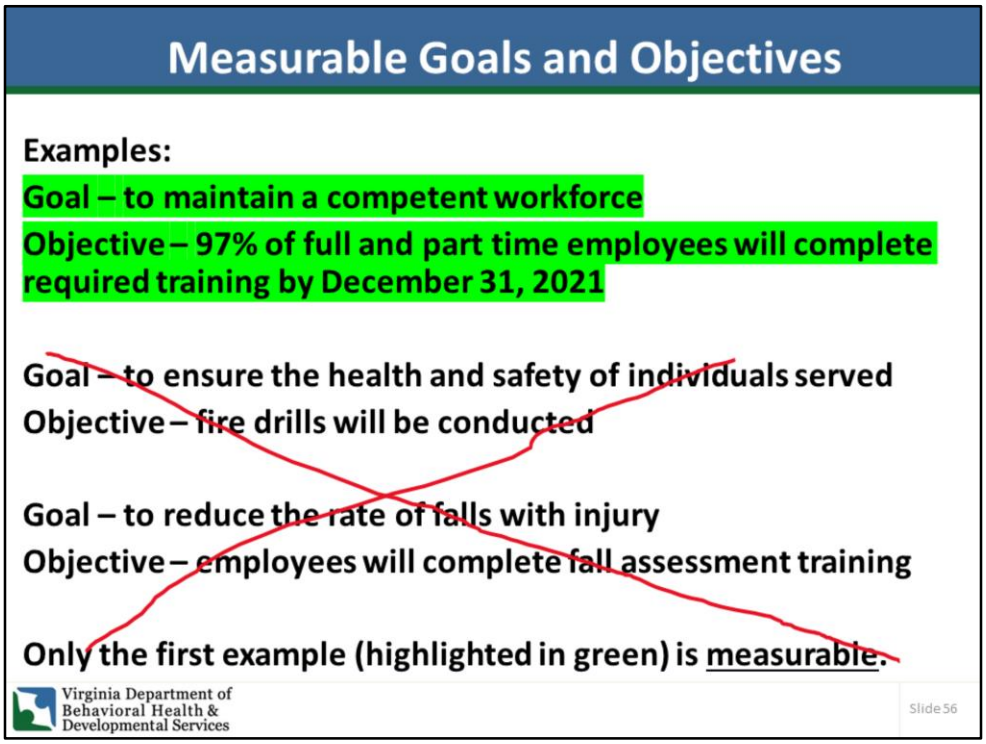
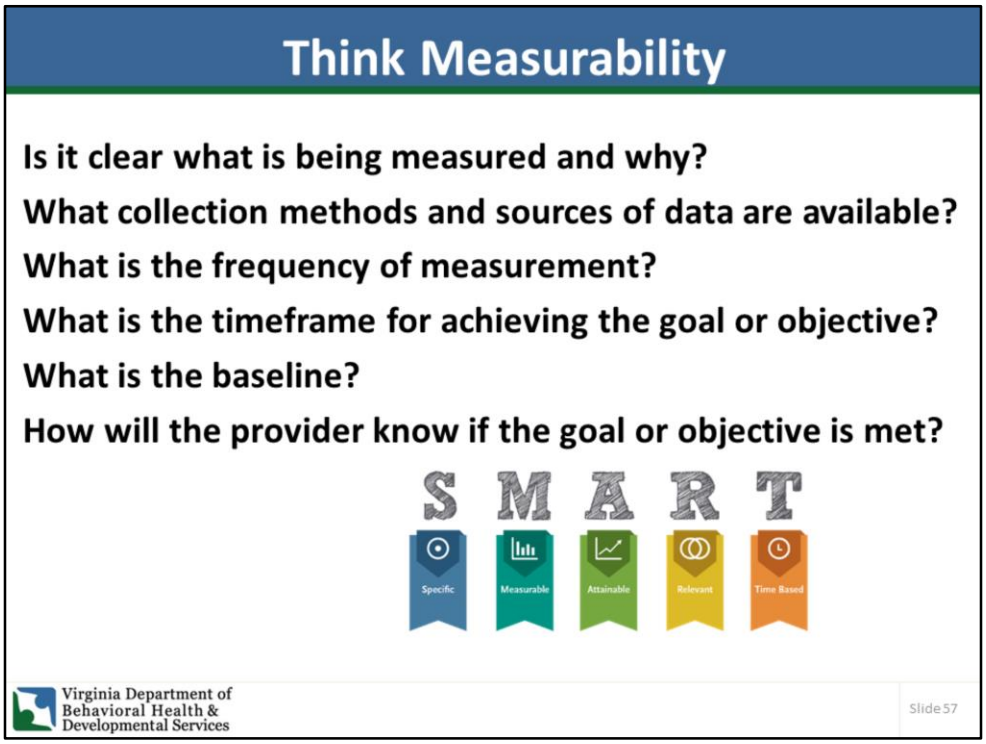


There is no requirement for a specific number of goals or objectives in the regulations. Every organization needs to decide what is most meaningful; focus on the most important; make sure everyone can understand the goal and that it is measurable.

Centers for Medicare and Medicaid Services (CMS) has a goal setting worksheet on its Quality Assurance Performance Improvement (QAPI) website. The information is included in the resources at the end of the presentation.



While all might be laudable, only the first example is really measurable. Some additional examples of measurable goals are included in the SAMPLE quality improvement plan posted to the Office of Licensing webpage as well as the Guidance for a Quality Improvement Program.



Many resources are available for developing goals and objectives (e.g. SMART Goals = Specific, Measurable, Attainable, Relevant, Time-Bound).

When establishing goals and/or objectives, be realistic (an attainable goal). Remember – some is not a number; soon is not a time. Be specific.

12VAC35-105-620.C.3

Include and report on statewide performance measures, if applicable, as required by DBHDS.

Currently, the statewide performance measures only apply to providers of developmental disability services. DBHDS is operationally collecting through WaMS and CHRIS.

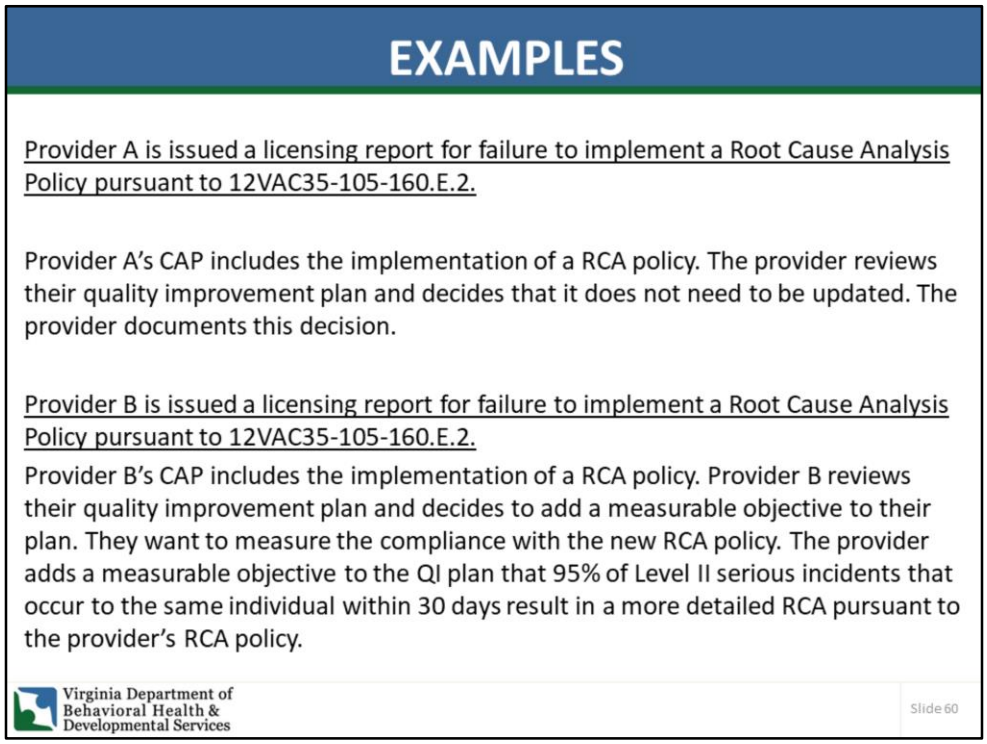
As this changes, DBHDS will notify providers.

12VAC35-105-620.C.4

Monitor implementation and effectiveness of approved corrective action plans pursuant to 12VAC35-105-170

Guidance for a Quality Improvement Program (November 2020)

"Providers are not required to update their quality improvement plan each time a licensing report is issued. However, anytime a provider is issued a licensing report, the provider should review their quality improvement plan to determine whether their current plan is sufficient to address the concerns identified in the licensing report and to monitor compliance with the provider's pledge CAP."



The examples demonstrate that it is the provider's decision whether to update the quality improvement plan when a corrective action plan is implemented. As noted in the Guidance for Quality Improvement, providers should have a clear written plan for how they will evaluate their current quality improvement plan to determine if it is sufficient to address the concerns identified in the licensing report and to monitor their pledged CAPs. The written plan shall include the person responsible for the reviews as well as how each review will be documented and stored, so that compliance may be determined by the licensing specialist during reviews.

The quality improvement plan should be dated and signed to indicate when it is implemented and when any updates occur.

12VAC35-105-620.C.5

Include ongoing monitoring and evaluation of progress toward meeting established goals and objectives.

Data monitoring can be an attachment to the provider's QI plan

Monitor data –

- implement quality improvement initiative
- respond to identified concerns

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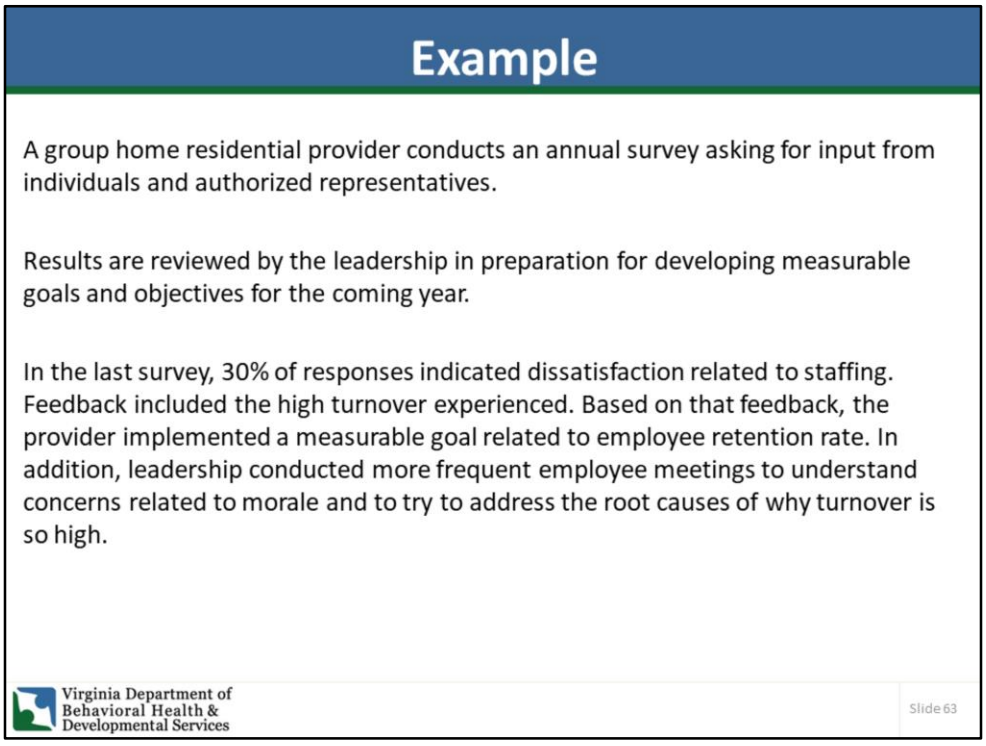
The quality improvement program includes the process of when and how the provider will review progress. This may occur a quality committee or council that regularly meets to review progress or through another structure. The process should include an analysis of data the organization is monitoring. The provider may want to implement a quality improvement initiative to address issues. A root cause analysis could be conducted to determine what systemic issues are preventing progress toward goals.

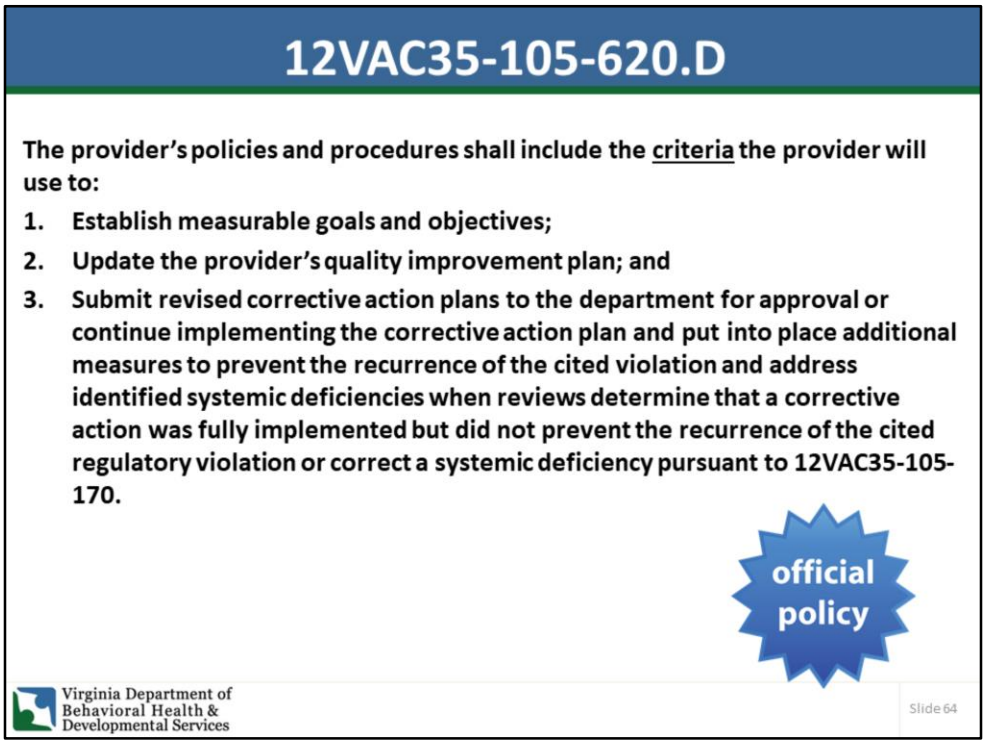
12VAC35-105-620.E

Input from individuals receiving services and their authorized representatives, if applicable, about services used and satisfaction level of participation in the direction of service planning shall be part of the provider's quality improvement plan. The provider shall implement improvements, when indicated.

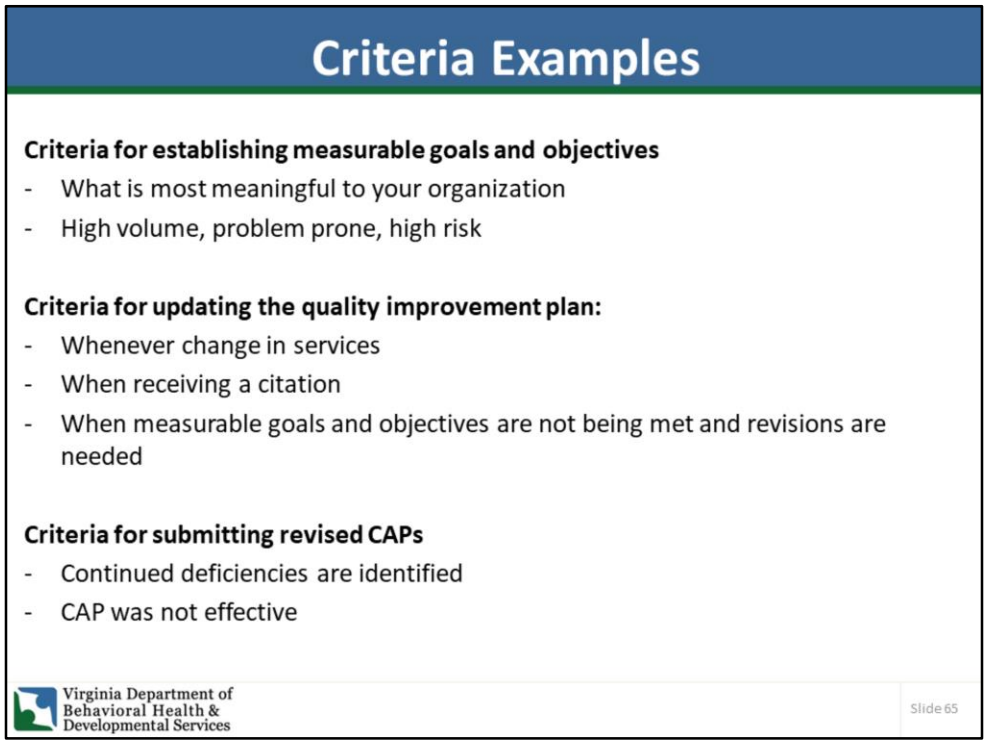
- No requirements for how often or how input is obtained
- Specific to your organization
- QI Plan outlines how/when AND what the provider does with the information obtained from customer satisfaction



The regulations do not require a survey. In this example, the provider conducts an annual survey.

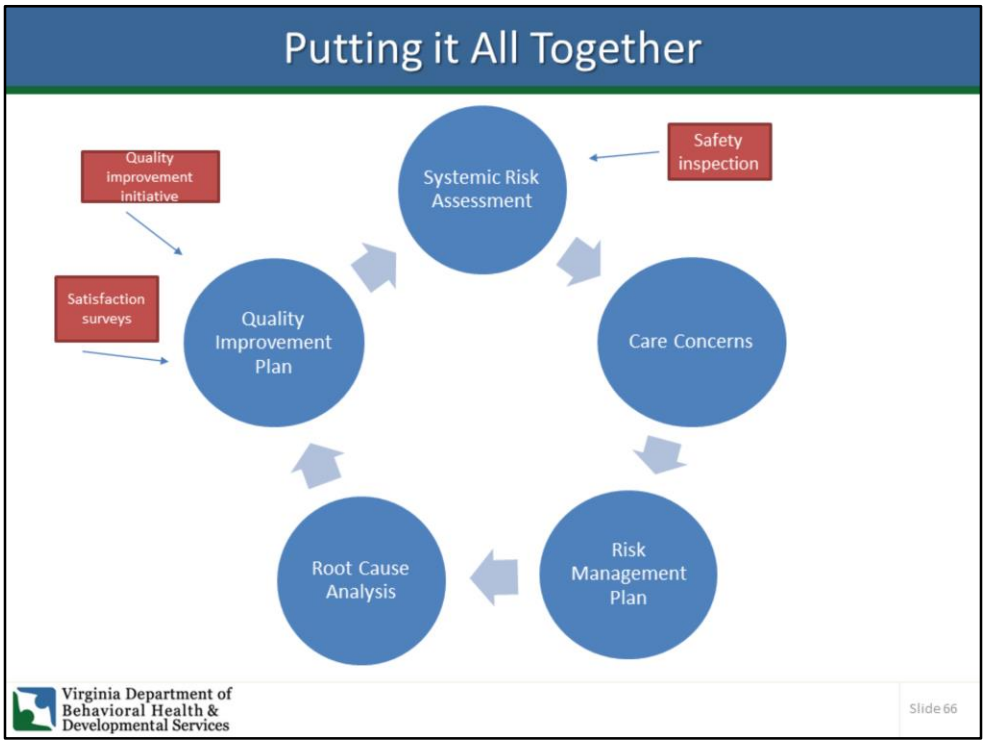


Reminder – this does not need to be included in your quality improvement plan – but in policy.



The criteria the provider develops depends on the organization size, etc.

The criteria for establishing goals and objectives could include input from employees (frontline staff), input or concerns raised as a result of satisfaction surveys, items that resulted in citations that need to be improved upon.



This non-directional cycle again shows how all parts are necessary in quality/risk management processes. A provider may utilize the results of their annual safety inspection in their systemic risk assessment. A provider may conduct satisfaction surveys to gather input for the quality improvement plan. A quality improvement effort may be initiated as a result of not meeting established goals and objectives.

Resources – OL Webpage

Guidance for Risk Management

https://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\GuidanceDocs\720\GDoc_DBHDS_6874_v3.pdf

Guidance for a Quality Improvement Program

https://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\GuidanceDocs\720\GDoc_DBHDS_6414_v3.pdf

Centers for Medicare and Medicaid Services

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/Downloads/ProcessToolFramework

Resources – OL Webpage

TRAINING AND TECHNICAL ASSISTANCE

BEHAVIORAL HEALTH ENHANCEMENT AND ASAM

- Aligning the Licensing Regulations with ASAM Criteria Training (April 2021)
- Memo Behavioral Health Enhancement and American Society of Addiction Medicine (March 2021)
- ICT/ACT Licensing Requirements Crosswalk (March 2021)

QUALITY IMPROVEMENT-RISK MANAGEMENT RESOURCES FOR LICENSED PROVIDERS

- Crosswalk of Approved Risk Management Training and DBHDS Risk Management Attestation (August 2021)
- Q&A from Risk Management – Quality Improvement Tips and Tools Training (August 2021)
- Risk Management – Quality Improvement Tips and Tools Training (June 2021)
- SAMPLE Provider Quality Improvement Plan (June 2021)
- SAMPLE Provider Risk Management Plan (June 2021)
- SAMPLE Provider Systemic Risk Assessment (June 2021)
- Quality Improvement – Risk Management Training (Updated March 2021)
- Q&A from November 2020 QI-RM-RCA Training (Updated March 2021)
- Risk Management & Quality Improvement Strategies Training by the Center for Developmental Disabilities Evaluat
- Risk Management & Quality Improvement Strategies Training by the Center for Developmental Disabilities Evaluat
- Quality Improvement – Risk Management Training (November 2020)
- Root Cause Analysis Training (November 2020)
- Q&A from November 2020 QI-RM-RCA Training (January 2021)

Questions

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Q&A

1. With the regulations for Quality Improvement and Risk Management does this require that we hire a person specifically for risk management and Quality Assurance, or can it be delegated to an administrator already within our company?

12VAC35-105-520.A requires each licensed service to designate a qualified person with responsibility for the risk management function. The provider may assign additional roles related to risk management depending on the size and scope of the provider's services. The job description of the person (responsible for the risk management function) should reflect that all or part of their responsibilities include those of the risk management function. One person can have risk management responsibilities for a provider's multiple services.

2. Does the person designated as the Risk Manager need to be onsite or could this be a corporate person that assists with reporting in CHRIS and with the organization?

The person designated as the risk manager has training pursuant to 12VAC35-105-520.A so that person may lead the team or ensure that the team completes its work in compliance with the provider's policy. The designated person should be familiar with the day-to-day operations of the service as well as familiar with the individuals served. The regulations do not require the person to be onsite.

3. Is this (risk assessment) done for each individual in program or one risk assessment for everyone?

12VAC35-105-520.C refers to the systemic risk assessment. As noted in the SAMPLE Systemic Risk Assessment, a systemic risk assessment is a careful examination of what the provider identifies as internal and external factors or situations that could cause harm to individuals served or that could negatively impact the organization. The risk assessment should lead to a better understanding of actual or potential risks and how best to minimize those risks. Systemic risk assessments vary depending on numerous factors such as an organization's size, population served, location, or business model.

Every organization will have different risks depending on the services provided, the location, the building (or buildings). Each provider needs to think about its potential risks. Please note the risk assessment must include the below components which apply to all locations.

1. The environment of care;
2. Clinical assessment or reassessment processes;
3. Staff competence and adequacy of staffing;
4. Use of high risk procedures, including seclusion and restraint; and
5. A review of serious incidents.

Q&A

12VAC35-105-520.D - The systemic risk assessment process shall incorporate uniform risk triggers and thresholds as defined by the department. The Department has defined these as care concerns.

A Risk Awareness Tool (RAT) is designed to increase awareness of the potential for a harmful event for individuals. Information related to the RAT can be found on the Office of Integrated Health webpage: Assuring Health and Safety for Individuals with Developmental Disabilities with a Comprehensive Risk Management Plan

4. Is the systemic risk assessment performed for each provider home (Sponsored residential program) or is it for the agency overseeing the SRP's?

Please note the risk assessment must include the below components which apply to all locations so data collected throughout the year from each location, individuals served would need to be incorporated into the risk assessment:

1. The environment of care;
2. Clinical assessment or reassessment processes;
3. Staff competence and adequacy of staffing;
4. Use of high risk procedures, including seclusion and restraint; and
5. A review of serious incidents.

As noted in the Guidance for Risk Management, environment of care considerations will be different when services are provided at a location that is not under the direct control of the provider, such as the individual's own home. While providers are more limited in their ability to assess some of the factors listed above in these locations, providers should consider any unique risks associated with the provision of services in these locations during its risk assessment review. In such cases the review does not need to consider each location (e.g. each home) individually, but should identify risks that may be common across the different locations or settings.

As also noted in the Guidance for Risk Management, a review of the environment of care should consider the results of the annual safety inspection conducted pursuant to 12VAC35-105-520.E, when applicable, but is broader than a safety inspection.

12VAC35-105-520.D – The systemic risk assessment process shall incorporate uniform risk triggers and thresholds as defined by the department. The Department has defined these as care concerns.

Q&A

5. Is quality assurance/risk management the same or should it be separated?

12VAC35-105-520 (Risk Management) includes the regulations related to risk management; 12VAC35-105-620 (Monitoring and evaluating service quality) includes the regulations related to quality improvement. Each provider should determine through its policies and procedures how risk management and quality improvement efforts will be coordinated. The Guidance for Risk Management states that a provider's risk management plan may be a standalone risk management plan or it may be integrated into the provider's overall quality improvement plan. Risk management plans and overall risk management programs should reflect the size of the organization, the population served, and any unique risks associated with the provider's business model.

6. Can we add goals to the QI Plan throughout the year, as long as we're still reviewing and updating our QI program/plan annually? If we meet this year's current goal for quality improvement, can we discontinue that, and add an additional goal?

12VAC35-105-620.D – the provider's policies and procedures shall include the criteria the provider will use to 1. Establish measurable goals and objectives; 2. Update the provider's quality improvement plan; and 3. Submit revised corrective action plans to the department for approval or continue implementing the corrective action plan and put into place additional measures to prevent the recurrence of the cited violation and address identified systemic deficiencies when reviews determine that a corrective action was fully implemented but did not prevent the recurrence of the cited regulatory violation or correct a systemic deficiency pursuant to 12VAC35-105-170. It is the provider's decision as to when the quality improvement plan is updated to include additional goals and/or to revise goals. The quality improvement plan should be dated and signed to indicate when it is implemented and when any updates occur.

7. If a provider decides that their QI Plan does not need to be updated in response to a citation, where should they document this decision?

The provider's policies and procedures for a quality improvement program should be followed in terms of where to document this decision. The Guidance for a Quality Improvement Program states that providers should have a clear written plan for how they will evaluate their current quality improvement plan to determine if it is sufficient to address the concerns identified in the licensing report and to monitor their pledged CAPs. The written plan shall include the person responsible for the reviews as well as how each review will be documented and stored, so that compliance may be determined by the licensing specialist during reviews.

Q&A

8. In terms of the Triggers and Thresholds for the Systemic Risk Assessment, are the Care Concerns only applied to an individual or are they also applied to the provider as a whole? For example, if a provider (as a whole) reports 3 or more serious incidents of any kind within 90 days, would this meet a Care Concern threshold? In CHRIS, the Care Concerns are divided into Individual and Provider Care Concerns with different criteria.

Care Concerns are specific to individuals. Initially, the OL was monitoring both Individual and Provider Care Concerns. After assessing the data, the Department has determined that monitoring individual care concern thresholds offers the most useful information for providers to assess if there may be a need to re-evaluate an individual's needs and supports, review the results of their root cause analysis or even consider making more systemic changes on a provider level.

9. If our licensing specialist has already reviewed and approved our QIP and Risk Management Plan/Program (approved Oct 2020) do we need to make modifications to meet newly revised/ clarified regulations or are we okay to review October 2021 with new goals/objectives for the agency?

The quality improvement and risk management regulations were effective November 2020. Each provider should review the regulations, as well as Guidance documents, quality improvement and risk management sample documents and training (all posted on the Office of Licensing webpage) to determine whether changes are necessary to ensure compliance. Quality improvement and risk management plans are often reviewed as part of investigations.

10. Risk Management has become a primary focus when licensing specialists review annually. Can we receive review and follow-up on the progress of plan and whether the plan is meeting regulations prior to annual licensing review?

If the provider received a citation related to risk management and their pledged Corrective Action Plan (CAP) was approved, the provider should be implementing the CAP and ensuring it is effective (refer to Guidance for a Quality Improvement Program and Guidance on Corrective Action Plans for more information on implementing a CAP).

Q&A

11. Can you provide us with the website or link to DMAS that gives samples of Goal setting/measurable goals and objectives you discussed earlier?

The goal setting worksheet mentioned in the training is from the Centers for Medicare and Medicaid Services (CMS). CMS Goal Setting Worksheet

12. On the licensing website under Guidance and Technical Assistance for Quality Improvement Risk Management Training (updated 3/21) when you open the document it is dated November 2020. Is that the correct one?

Based on a review of data, the Office of Licensing determined that it is more beneficial to individuals and providers to focus only on individual care concerns. It should be noted that providers are required to develop a Root Cause Analysis policy in accordance with the regulations (12VAC35-105-160.E.2) and with their own internal determinations which allows providers to independently track and trend provider care concerns they think may be important. The training provided in November 2020 was updated to reflect this decision to focus on only individual care concerns.

13. Will another attestation letter be provided for this training or are we allowed to add this training on the current form?

The Office of Licensing updated the Crosswalk of Approved Risk Management Training and will post on the webpage in August 2021.

Crosswalk of DBHDS Approved Risk Management Training and Attestation